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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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

CELSUS THERAPEUTICS PLC
(Exact name of registrant as specified in its charter)

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

53 Davies Street
London WIK 5JH
United Kingdom
(Address of principal executive offices)

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

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

Title of each class	**Name of each exchange on which registered**
American Depositary Shares, each representing ten (10) Ordinary Shares, par value £0.01	The NASDAQ Stock Market LLC

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

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ [Do not check if a smaller reporting company]	Smaller reporting company ☒

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

The aggregate market value of the registrant's voting and non-voting ordinary shares held by non-affiliates of the registrant on June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $34,494,495 based upon the closing price reported for such date on the NASDAQ Capital Market.

As of February 11, 2015, the registrant had 55,636,283 ordinary shares outstanding. 45,582,789 shares held as American Depositary Shares (ADSs),

each representing 10 ordinary shares, were outstanding as of February 11, 2015.

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Forward-Looking Statements

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

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

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

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

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

PART I

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

Item 1. BUSINESS

Overview

Celsus Therapeutics Plc is a biopharmaceutical company dedicated to the discovery and development of novel, first-in-class, non-steroidal, synthetic anti-inflammatory drugs. We believe that we have developed a new class of synthetic drugs for therapeutic purposes that we term Multifunctional Anti-Inflammatory Drugs, representing a new multi-drug platform for the treatment of a wide range of inflammatory diseases and conditions. For decades, steroids have been the most commonly used anti-inflammatory drugs in the world, used extensively to treat inflammatory diseases and allergies. However, steroids are associated with severe side effects, such as metabolic changes, weight gain, changes in blood pressure, diabetes, osteoporosis, cataract and glaucoma, psychosis and depression. These side effects have led to reluctance by medical providers and their patients to use these drugs, providing an unmet need in multiple disease markets for safer alternatives to steroids.

In general, inflammation is a defense mechanism, part of our immune system, protecting our bodies from infection. However, when inflammation is triggered for the wrong reasons (i.e., not as a reaction to infection) or is unable to shut down, this results in an inflammatory disease. Since each organ in the body is capable of protecting itself from infections using inflammation, each organ can suffer from an inflammatory disease or condition.

Inflammatory diseases therefore manifest in a wide range of symptoms, affecting many organs in the body and have diverse causes. Inflammatory diseases encompass such diverse illnesses as respiratory diseases including allergic rhinitis, asthma, and chronic obstructive pulmonary disease alpha-1-antitrypsin, bronchiectasis, cystic fibrosis; chronic gastrointestinal diseases such as Crohn's disease and ulcerative colitis; skin inflammations such as dermatitis, eczema, psoriasis and rosacea; cardiovascular diseases such as restenosis, thrombosis and acute cardiovascular syndrome; diseases of the eye such as dry eye, uveitis, and conjunctivitis; diseases such as arthritis and related diseases such as osteo-arthritis and rheumatoid-arthritis; autoimmune disorder such as Lupus, Wegener's granulomatosis, and dermatomyositis; and disease of the central nervous system such as multiple sclerosis. However, while the causes and symptoms of these diseases are diverse, their treatment is often the same: anti-inflammatory drugs.

Product Candidates

Our lead clinical candidate is MRX-6, a topical cream intended for treating atopic dermatitis, a common type of eczema. The Phase 2a clinical trial for MRX-6 cream 1%, which was conducted as an academic study and, therefore was not compliant with the regulatory requirements of the U.S. Food and Drug Administration, or FDA, and other regulatory authorities. A second, multi-center, vehicle controlled, double blind, dose ranging study of MRX-6 cream 2% clinical trial was carried out in in Israel. Results of the trial were reported on May 8, 2013. These results demonstrated that MRX-6 cream 2% appeared to be a safe and effective treatment for chronic hand eczema secondary to contact dermatitis, similar to the results we saw in our earlier Phase 2a trial. The data announced on May 8 were from a multi-center Phase 2 double blind, vehicle controlled trial of MRX-6 cream 2% for the treatment of patients with chronic hand eczema due to allergic contact dermatitis. The results showed a 56% improvement in symptoms such as dryness, scaling, redness, pruritus and fissures from baseline in the MRX-6 treated hand/forearm, compared to a 24% improvement for vehicle treated hand/forearm ($p < 0.0001$). Each patient acted as his or her own control. Clinically significant benefit, defined as an equal to or greater than 50% reduction in symptoms from baseline in the MRX-6 treated hand/forearm was seen in 67% of patients. MRX-6 was found to be safe and well-tolerated and we did not observe any adverse events. The benefit was similar regardless of patient baseline score, study center or symptom sub-score.

We are currently conducting a double-blind, parallel-group, vehicle-controlled clinical trial to evaluate the safety and efficacy of MRX-6 cream 2% in a pediatric population with mild to moderate atopic dermatitis. This trial randomized 74 patients into a four-week double-blind period, followed by a four-week open label extension for those patients who wish to continue in the trial. We anticipate completing the double-blind portion of this Phase 2 MRX-6 cream 2% clinical trial by the end of February, 2015. We submitted the IND for MRX-6 cream 2% in December 2014 and announced FDA allowance of the IND in January 2014.

We also intend to undertake, depending on available resources, pre-clinical studies for other product candidates: OPT-1, for the treatment of ophthalmic inflammation; CFX-1, for the treatment of cystic fibrosis; OAX-1, for the treatment of osteoarthritis; and potentially other inflammatory disorders. Given the common biochemical mechanism of all inflammatory diseases, we plan to gradually expand the application of our platform technology for our product candidates to other forms of inflammatory diseases in the future, such as inflammatory bowel disease, or IBD, eosinophilic esophagitis, nasal polyps, etc.

Our corporate headquarters are located at 53 Davies Street, London W1K 5JH, United Kingdom, telephone +44-203-318-3004, and our registered office is located at Thames House, Portsmouth Road, Esher, Surrey KT109AD, United Kingdom. Our US offices are located at 24 West 40th Street, 8th Floor, New York, NY 10018, telephone 646-350-0702.

Our Strategy

Our business strategy is to expand and build our biopharmaceutical business to gradually focus on a spectrum of inflammatory diseases based on our current and upcoming first in class product candidates, that we believe will fill the current unmet need for safe and potent alternatives to steroids. As a drug development company, most of our efforts and resources to-date have been devoted to performing research and development, conducting pre-clinical studies and clinical trials, developing and protecting our intellectual property and raising capital. We intend to enter into strategic licensing arrangements with pharmaceutical companies for the commercialization of our drugs. This process will involve completing our clinical trials and obtaining regulatory approvals for marketing, distribution and sale of our drugs. We also intend to continue to expand the range of our products by gradually targeting additional types of inflammatory diseases.

We currently perform our research and development activity mainly through outsourcing to subcontractors. Our board of directors, which consists of recognized professionals in the fields of biology, medicine and finance, regularly approves our material contracts with subcontractors.

Our unique lead product candidates are first-in-class, novel, non-steroidal, synthetic anti-inflammatory products that address the need to inhibit sPLA2 in a broad-ranged manner while avoiding any interference with the homeostatic cPLA2 family. The lipid inhibiting moiety is responsible for inhibiting sPLA2 in a unique and broad-ranged manner while the glycosaminoglycans, or GAGs, prevent the drug's penetration into the cell and any possible interference with cPLA2. Thus, unlike previous attempts at inhibiting sPLA2, our product candidates remain on the cell surface and target the pathology-associated secretory PLA2 isomers or sPLA2, but do not interfere with the homeostatic isomers found inside the cell.

Steroids and Currently Available Alternatives

Steroids are the most commonly prescribed medications for inflammatory diseases because of their high potency and formulation flexibility but are limited by their side effects that include hypertension, high glucose levels, obesity, brittle bones/osteoporosis, immunosuppression, glaucoma and psychosis. Thus, safer yet potent alternatives to steroids have long been sought to provide this unmet need. However, current alternatives to steroids, while often commercially successful, are less potent than steroids, have limited formulation flexibility and have their own potential safety concerns. Similarly, topical steroids which are used to treat skin inflammation instead of oral steroids, can be less potent than the oral versions and have potential safety concerns that relate to the risk of systemic corticosteroid absorption and include adrenal suppression, bond fracture among the elderly, and reduced bone growth and height in children. Adverse local effects of topical steroids may include skin thinning, stretch marks, acne, testicular atrophy, nosebleeds, stinging, burning and dryness.

We believe that our product candidates will provide safer and more effective treatment than the current alternatives to steroids without the adverse side effects associated with steroids.

The drugs used to treat inflammatory diseases are broadly divided into two groups: steroids and non-steroidal drugs. Non-steroidal drugs, in turn, can be categorized into synthetic drugs, which include our product candidates, and biological drugs such as monoclonal anti-bodies.

Non-steroidal synthetic drugs include the old generation of non-specific COX inhibitors, such as ibuprofen and aspirin, and a newer generation of specific inhibitors of COX-2, such as Celebrex® and Vioxx®. COX inhibitors are drugs that inhibit the action of the COX enzyme, which is responsible for producing factors that cause inflammation. The old generation of COX inhibitors is associated with severe gastrointestinal adverse effects. The newer generation of specific COX-2 inhibitors, originally designed to be safer, has subsequently been found to have side effects, including primarily cardiovascular complications. These side effects have led to the withdrawal the drug Vioxx® from the market and specific warnings for Celebrex®.

Non-steroid biological drugs are used to treat severe cases of inflammation. These drugs are derived from proteins, i.e., they are produced from live cells and not by way of chemical synthesis. Examples of this type of drug are Enbrel® and Remicade®, which are used for treating severe rheumatoid arthritis and psoriasis as well as IBD. These drugs have a number of disadvantages: the drug administration is limited to injection/IV, their cost is very high and they are associated with rare but severe side effects.

In cystic fibrosis, a genetic disorder that leads to severe lung inflammation and bronchiectasis, amongst other clinical problems, inhaled steroids have not demonstrated benefit, although high dose ibuprofen has been shown to be somewhat effective in treating lung inflammation. However, according to the Cystic Fibrosis Foundation 2012 Patient Registry Annual Data Report, only 3.3% of cystic fibrosis patients who were eligible for ibuprofen were prescribed ibuprofen, in part due to concerns about side effects.

The drugs for treating mild to moderate atopic dermatitis can be divided into two primary groups: topical steroids, which are the most common treatment for atopic dermatitis, and TCIs such as Elidel® and Protopic®.

Other than topical steroids, TCIs are the only category of topical anti-inflammatory drugs aimed specifically at treating the inflammatory aspect of skin diseases. Elidel® and Protopic® are identical in their mechanism of action. TCIs are generally inferior to steroids with the primary indication being children (who tend to respond better and for whom steroidal side effects are heightened). Elidel (Novartis) was launched in the United States in 2002 and Protopic (Astellas) in 2001. Both are prescribed as second-line therapy in order to avoid the use of topical steroids. In 2005, the FDA required the labeling of both drugs to include a “black box” warning regarding risks of carcinogenicity. The sales of both drugs have declined significantly. The Elidel franchise was sold to Meda in 2011 for $420 million.

According to IMS Data, a leading market research company, approximately 40 million prescriptions for topical steroids were written in the United States in 2013.

The following table provides a comparison of properties of different drug groups that are in development or on the market:

Class	Efficacy	Examples	Side Effects
Group A — steroids			
Steroids	**Effective; affect a wide range of inflammatory mediators**	**Beconase®, Flonase®, Rhinocort®, Dermovate®, Nasonex®, Synalar®, Topicort®**	**Extensive effects in chronic use including the following specific ones for intranasal sprays (INS) and topical (skin) steroids:**
			Nasal sprays: **Systemic effects: adrenal suppression, hyperglycemia, bone demineralization/ fracture, growth delay in children. Local effects: increased intraocular pressure, cataract formation, nasal septal atrophy, fungal infection, nosebleeds, stinging, burning, dryness, smell and taste abnormalities** ***Topical (skin) steroids:*** **Local: atrophy, skin fragility, striae, purpura (itching), telangiectasia acne, contact dermatitis, rosacea, delayed wound healing, scarring, infections (local) Systemic: cataracts, glaucoma**
Group B — non-steroid synthetic drugs			
COX inhibitors	**Low potency; primarily used mainly as mild painkillers**	**Aspirin, ibuprofen, voltaren, etc. (typically pills)**	**Gastrointestinal bleeding and ulcers**
Specific COX-2 inhibitors	**Low potency; primarily used mainly as mild painkillers**	**Celebrex®, Bextra®, Vioxx®**	**Gastrointestinal side effects and Cardiovascular effects led to the recall of Vioxx**
LOX and Leukotriene inhibitors	**Mild efficacy**	**Singulair®, Zyflo®, Accolate®**	**Liver toxicity (Zyflo®), Risk of infections (particularly lung infections such as pneumonia and TB), risk of cancer (particularly Lymphoma)**
Non-steroid biological drugs			
Antibodies and recombinant receptors	**Varies with patients.**	**Enbel®, Remicade®, Raptiva®, Humira®, Xolair®**	**Risks of infections, particularly pulmonary infections such as pneumonia and TB. Risks of certain types of cancers, particularly lymphoma. Rare but potentially very dangerous exacerbated by very long duration of drug activity in body**

Class	Efficacy	Examples	Side Effects
Our Product Candidates			
Our Product Candidates	**Currently in phase 2 clinical trials; studies indicate favorable safety and promising efficacy**	**A number of compounds that are candidates for drugs with wide formulation flexibility**	**To date, no treatment emergent adverse events noted but further investigation is needed**

Scientific Background to Inflammation and Our Product Candidates

The phospholipase A2 (PLA2) is a super-family of enzymes responsible for triggering the inflammatory response in the body. This enzyme family includes two sub-families of PLA2 that are of particular interest to anti-inflammatory drug development: the secretory (sPLA2) and the cytosolic (cPLA2) families. The sPLA2 enzyme family consists of at least 13 sub-types (isoforms) and plays a key role in launching inflammation associated with pathogenesis and high levels of sPLA2 have been found in every inflammatory disease studied to date although these enzymes are not necessary to the cell in the absence of inflammation. These enzymes are located outside the cell and are generated and secreted by white blood cells (part of the immune system) but have also been found to be produced by any cell undergoing inflammation. sPLA2 hydrolize cell-membrane phospholipids to produce two critical inflammatory pre-cursors in the cell (arachidonic acid and lysophospholipids). These precursors are the substrates for several complex metabolic pathways that give rise to dozens of signaling molecules that generate inflammation (pro-inflammatory mediators). Those derived from arachidonic acid are termed eicosanoids and include prostaglandins and thromboxanes (generated via the COX pathway), as well as the leukotrienes and the expoxins (generated via the LOX pathway). Those derived from lysophospholipids induce activation and extravasation of leukocytes, histamine secretion by mast cells, can induce tissue damage such as gastric ulceration, act as a growth factor (especially lyso-phosphatidic acid). They are also the precursors of PAF, a potent mediator of inflammatory processes. In contrast to the sPLA2 enzymes, the cPLA2 family of enzymes, consisting of at least four isoforms, is located exclusively within the cell and is vital to the functioning of the cell at all times (homeostatic). This family does not play a direct role in triggering or maintaining inflammation associated with pathogenesis and its function seems to be the maintenance of the basal level of inflammatory mediators in the normal cell.

Both COX and LOX have been therapeutic targets for anti-inflammatory drugs for decades. Examples include the COX inhibitors Aspirin and ibuprofen, the COX-2 inhibitors Celebrex and Vioxx and the LOX/leukotriene inhibitors Singulair® and Zyflo. The relatively poor potency of COX and LOX inhibitors is directly related to the fact that they do not affect the activity of the sPLA2 family of enzymes and can therefore not exert an inhibitory effect on the inflammatory process at its inception. Their side effect profile is similarly related to their ability to inhibit only a sub-section of the inflammatory pathway which, in turn, leads to over-stimulation of parallel pathways and the resulting damage.

Market opportunity in inflammatory diseases

The term “inflammatory diseases” applies to a super-family of diseases and conditions comprising the largest such group with hundreds of distinct diseases. These include autoimmune diseases, allergies, reactions to infections and tissue breakdown, hereditary diseases as well as diseases of unknown etiology. Increasingly, many cancerous processes such as angiogenesis are also being linked to inflammation. Names of inflammatory diseases typically have the suffix “— itis” such as bronchitis, appendicitis, dermatitis, but many other do not such as asthma, psoriasis, lupus, etc. According to a published report by GBI Research, the global drug market for inflammatory diseases was approximately $57 billion in 2009.

MRX-6 and the market for dermatitis (eczema)

MRX-6 is a topical cream aimed at treating eczema with our first indication being atopic dermatitis. There is a wide variety of medical conditions that fall under the broad definition of dermatitis/eczema, including contact dermatitis, atopic dermatitis and seborrhea dermatitis. The first is an allergy, the second is of unknown etiology but probably autoimmune in nature and the last is an abnormal reaction to normal skin flora. All forms of eczema may cause discomfort, pain and embarrassment to the person affected. The incidence of atopic dermatitis, for example, has increased significantly over the past 30 years in the industrialized world, probably due to environmental factors.

The drugs for treating mild to moderate dermatitis can be divided into two primary groups: topical steroids, which are the most common treatment for dermatitis, and TCIs such as Elidel® and Protopic®.

Topical Steroids

Topical steroids have dominated the market for decades and are commonly used. Dozens of varieties are available from low-strength over-the-counter versions to potent prescription drugs. Examples of such prescription drugs in the US market include Synalar, Kenalog, Elocon, Ultravate, Temovate, Halog and Topicort.

They are associated with side effects both local and systemic, including:

- Local: atrophy, skin fragility, striae or stretch marks, purpura or itching, telangiectasia acne, contact dermatitis, rosacea, delayed wound healing, scarring, local infections, and testicular atrophy.
- Systemic: cataracts, glaucoma, short stature, Cushing's syndrome, and hypothalamic-pituitary-axis suppression.

Topical Calcineurin Inhibitors

TCIs are the only commonly used category of topical anti-inflammatory drugs aimed specifically at treating the inflammatory aspect of the disease. They are generally inferior to steroids with the primary indication being children (who tend to respond better and for whom steroidal side effects are heightened). Elidel was launched by Novatris in the United States in 2002 and Astellas launched Protopic in 2001. Both are prescribed as second-line of treatment if patients are unresponsive to steroids but, in reality, would be frequently prescribed to avoid the use of topical steroids for safety issues. At the height of sales (2005), these drugs had combined global sales of $550 million. In 2005, the FDA assigned both drugs to a "black box" warning stipulating risks of carcinogenicity. The sales of both drugs have declined significantly. The Elidel franchise was sold to Meda Pharmaceuticals Inc. in 2011 for $420 million.

According to IMS Data, a leading market research company, approximately 40 million prescriptions for topical steroids were written in the United States in 2013.

Development of our Clinical Pipeline for our Product Candidates

We are currently clinically developing MRX-6 for the treatment of dermatitis. In addition, we are in the pre-clinical stages of developing three product candidates for: ophthalmology such as conjunctivitis and dry eye, cystic fibrosis, osteoarthritis and other inflammatory indications.

Clinical advancement of our lead product candidates

We are currently conducting a double-blind, parallel-group, vehicle-controlled clinical trial to evaluate the safety and efficacy of MRX-6 cream 2% in a pediatric population with mild to moderate atopic dermatitis. This trial randomized 74 patients into a four-week double-blind period, followed by a four-week open label extension for those patients who wish to continue in the trial. We anticipate completing the double-blind portion of this Phase 2 MRX-6 cream 2% clinical trial by end of February, 2015. We submitted an IND for MRX-6 cream 2% in December 2014, and announced FDA allowance of the IND in January 2015.

MRX-6

Pre-clinical and Phase 1 clinical trials. From 2005 to 2007, we conducted pre-clinical development of the drug, which included studies in animal models. In 2007, we conducted an initial, exploratory size trial (a first in-patient study) on 11 patients who suffered from contact dermatitis with the primary objective of determining initial efficacy in treating humans. The clinical trial was conducted under the supervision of Prof. Arieh Ingber, head of the Dermatology Department at Hadassah Ein-Kerem Hospital in Israel. The patients were treated for 28 days with MRX-6 cream 1% (morning and evening) and double-blinded with vehicle. The results showed significant clinical efficacy compared to the vehicle group (70% improvement compared to 37% in the placebo group ($p = 0.0024$)), with efficacy being comparable to the common efficacy of steroid ointments. The efficacy is based on a standard medical index for assessing improvement in disease. Further, no drug-related adverse effects were identified. The results of this clinical trial were published in March 2007 in the International Journal of Inflammatory and Immunopathology. From 2007 to early 2010, we further developed the chemical synthesis and formulation of MRX-6.

Phase 2 clinical trials

We have completed first-in-patient clinical trials (Phase 2a) of the MRX-6 cream 1%, a topical cream intended for treating contact dermatitis (a common type of eczema). This Phase 2a clinical trial for MRX-6 cream 1% was conducted as an academic study and, thus, is not FDA-compliant. We also conducted a Phase 2 clinical trial for MRX-6 cream 2% which was also an academic study. The MRX-6 cream 2% study was conducted on 30 patients at Hadassah Ein-Karem Hospital and Laniado Hopsital in Israel. Patients were treated for 21 days (morning and evening) with the same tests as we conducted in the Phase 2a trial. Although MRX-6 was approved by the local Institutional Review Board and the Israeli Ministry of Health, this clinical trial was conducted as an academic study, and does not comply with FDA's good clinical practice requirements. While the FDA will not approve a drug based on academic studies, companies do routinely submit results of academic studies as supportive evidence.

On May 8, 2013, we announced positive results from a multi-center Phase 2 double blind, vehicle controlled trial of MRX-6 cream 2% for the treatment of patients with chronic hand eczema secondary to allergic contact dermatitis (ACD).

Data released were for treatment with MRX-6 cream 2% and vehicle control. The results show a 56% improvement in symptoms such as dryness, scaling, redness, pruritus and fissures, from baseline in the MRX-6 treated hand/forearm, compared to a 24% improvement for vehicle treated hand/forearm ($p < 0.0001$). Each patient acted as his or her own control. Clinically significant benefit, defined as an equal to or greater than 50% reduction in symptoms from baseline in the MRX-6 cream 2% treated hand/forearm was seen in 67% of patients. MRX-6 cream 2% was found to be safe and well-tolerated, with no adverse events reported. The benefit was similar regardless of patient baseline score, study center or symptom sub-score.

Table 1 . Percent Change from Baseline to Day 21 — Comparison between treatment groups using Paired T-test/Wilcoxon Rank Sum Test — ITT population (N = 30)

Endpoint		MRX-6	Vehicle	P-Value
Total Physicians Visual Assessment	Mean % Change from Baseline	-56%	-24%	<0.0001
Scaling*	Mean % Change from Baseline	-45%	-22%	0.0130
Redness*	Mean % Change from Baseline	-47%	-20%	0.0006
Pruritis*	Mean % Change from Baseline	-63%	-28%	0.0059
Fissures*	Mean % Change from Baseline	-79%	-44%	0.0045
Dryness*	Mean % Change from Baseline	-46%	-15%	0.0008

* Data are not normally distributed — P-Values result from Wilcoxon Rank Sum test.

We are currently conducting a double-blind, parallel-group, vehicle-controlled clinical trial to evaluate the safety and efficacy of MRX-6 cream 2% in a pediatric population with mild to moderate atopic dermatitis. This trial randomized 74 patients into a four-week double-blind period, followed by a four-week open label extension for those patients who wish to continue. We submitted our IND to the FDA for MRX-6 cream 2% in December 2014 and announced FDA allowance of our IND in January 2014 so that we may conduct clinical trials in the United States.

Advancement of our additional research and development programs

We also plan, depending on available resources, to initiate a number of pre-clinical studies for the development of drugs for inflammatory eye diseases, OPT-1; cystic fibrosis, CFX-1; osteoarthritis, OAX-1; and other inflammatory diseases. We intend to conduct such studies throughout 2015. OPT-1 pre-clinical studies planned to take place during 2015 include synthesizing and formulating the drug, conducting safety studies and animal models. Potential CFX-1 pre-clinical studies are intended to take place beginning in the first half of 2015, in which we intend to synthesize and formulate the drug, conduct safety studies and animal models. OAX-1 pre-clinical studies planned to take place during 2015 include synthesizing and formulating the drug, conducting safety studies and animal models.

No treatment-related side effects were observed for any of the trials performed. All side effects recorded shared the same prevalence as the placebo group and do not therefore result from treatment with the specific drug.

Intellectual Property

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

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

We have an exclusive license from Yissum for patents and patent applications that cover our product candidates MRX-5, MRX-6, OPT-1, CFX-1 and OAX-1 in the United States, Canada, Australia, Japan, before the European Patent Office designating Germany, Great Britain, Spain, France, Italy, and other European Union Countries, as well in certain other countries outside those regions. We have also exclusively licensed from Yissum patents and pending patent applications in the United States, Canada, Australia, Japan, before the European Patent Office designating Germany, Great Britain, Spain, France, Italy, and other European Union Countries, as well in certain other countries outside those regions for the use of our product candidate MRX-6, OPT-1, CFX-1 and OAX-1 for treating patients having contact dermatitis, MRX-6; conjunctivitis and dry eye, OPT-1; cystic fibrosis, CFX-1; and osteoarthritis, OAX-1.

We own or have exclusive rights to 24 United States and 21 foreign issued patents and allowed patent applications, and 11 United States and 49 foreign pending patent applications, as well as two (2) pending international patent applications. Issued patents which cover our product candidates MRX-6, OPT-1, CFX-1 and OAX-1 in the United States, will expire between 2021 and 2022, depending on the specific product candidates. Issued patents directed to our product candidates, MRX-6, OPT-1, CFX-1 and OAX-1 outside of the United States, will expire in 2021. We have pending patent applications for formulations of our product candidates , MRX-6, OPT-1, CFX-1 and OAX-1 that, if issued, would expire in the United States and in countries outside of the United States between 2021 and 2032, depending on the specific compositions and formulations: contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), cystic fibrosis (CFX-1) and osteoarthritis (OAX-1). We have an issued patent directed to methods of manufacturing which covers our product candidate compounds in the United States and which will expire in 2021. Issued patents directed to methods of treatment using our product candidates, MRX-6 and OPT-1 in the United States, will expire between 2021 and 2024, depending on the specific indication: contact dermatitis (MRX-6), conjunctivitis (OPT-1). Issued patents directed to use of our product candidate: MRX-6, OPT-1 and CFX-1 for indications outside of the United States, will expire between 2021 and 2026, depending on the specific indication: contact dermatitis (MRX-6), conjunctivitis (OPT-1), and cystic fibrosis (CFX-1). We have pending patent applications for use of our product candidates MRX-6, OPT-1, CFX-1 and OAX-1 that, if issued, would expire in the United States and in countries outside of the United States between 2021 and 2032, depending on the specific indications and formulations: contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), cystic fibrosis (CFX-1) and osteoarthritis (OAX-1).

Any patent applications which we have filed or will file or to which we have licensed or will license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our products or technology, or may be subsequently circumvented, invalidated or narrowed, or found unenforceable. Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to successfully defend a patent challenge or to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a materially adverse effect on our business.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for, or useful to, the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and methods could be limited or prohibited.

Material Licenses

License Agreement with Yissum

Our research and development programs are based on technology that was licensed from Yissum, Research & Development Company of the Hebrew University of Jerusalem, or Yissum, where Prof. Yedgar, conducted studies focused on inflammation. Prof. Yedgar is a Professor Emeritus and a research lab chief, and has no management position, voting power or other significant influence with respect to the Hebrew University or Yissum.

Prof. Yedgar performed these studies during his employment as a retired Prof. at the Department of Biochemistry of the Hebrew University of Jerusalem. Thus, except for Prof. Yedgar having the right to receive any distribution of dividends, Prof. Yedgar and his heirs have the right to receive 60% of the net income that would be distributed by the Company to Yissum.

On November 27, 2002, Celsus USA entered into an exclusive license agreement, which we refer to as the License Agreement, with Yissum Research and Development Company of the Hebrew University in Jerusalem, or Yissum. Pursuant to the License Agreement, Celsus USA was granted an exclusive, worldwide license, including a right to sublicense (subject to the prior written consent of Yissum), to make, have made, use, market, sell, have sold, offer to sell, import, license and distribute the technology owned by Yissum for the use of lipid conjugates for the treatment of disease. Unless earlier terminated, the term of the License Agreement is the later of 20 years from the date of the License Agreement and the term of the patents or patent applications. On February 1, 2005, the License Agreement was sublicensed from Celsus USA to us pursuant to an exclusive sublicense agreement which will terminate upon the termination of the License Agreement.

Under the terms of the License Agreement, we will pay to Yissum royalties on a quarterly basis, as follows: a percentage (4%) of the net sales, or if we receive sublicensing revenue from third parties, we will pay a royalty of 18% of the sublicensing revenue received. “Net sales” is defined under the License Agreement as the amount billed by us, our affiliates or distributors to third parties (other than sublicensees) for sales of licensed products, less (i) customary discounts, (ii) sales, tariff duties, use taxes including VAT and (iii) outbound transportation costs, credits, returns, export licenses, import duties, value added tax and prepaid freight. “Sublicensing revenue” is defined as all cash, fees and royalties paid to us by the sublicensee in consideration for the granting of rights to the patents and/or use the licensed technology, excluding any reimbursements for expenses directly attributable to the conduct of clinical development and/or trials by us.

We have undertaken, at our own expense, to use our commercially reasonable best efforts to develop the licensed products under the License Agreement and to be responsible for the preparation, filing prosecution and maintenance of all the patents. The intellectual property rights of the licensed technology are, and will remain, owned by Yissum. We assume full responsibility and conduct of patent prosecution and maintenance of the intellectual property. Any application for registration of a patent will be registered exclusively to the title of Yissum, is subject to the approval of Yissum and will be made at our full expense. We have undertaken, at our own expense, to provide full protection against third party’s infringement of the intellectual property.

We have undertaken to indemnify Yissum or any person acting on our behalf, against any liability, including product liability, damage, loss or expense derived from the use, development, manufacture, marketing, sale or sublicensing of the license product and technology.

If we default or fail to perform any of the terms, covenants, provisions or our obligations under the License Agreement, Yissum has the option to terminate the License Agreement, subject to advance notice to cure such default.

Manufacturing, Marketing and Sales of our Drugs

Synthetic drugs, such as those being developed by us, are based on a chemical manufacturing process that requires raw materials, such as various solvents, sugars, fats and polymers. There are many suppliers of raw materials for these products and, in recent years, no material changes have occurred in the prices of the raw materials that are required for the research, development and manufacturing of the drugs we are developing.

We currently have no in-house manufacturing or development capabilities, and have no current plans to establish laboratories or manufacturing facilities for significant clinical production. We currently have our products manufactured by Scynexis, Inc. Our Agreement with them is subject to industry-standard terms and conditions, and drug product manufacture is performed on an as-needed basis.

We have no direct experience in synthesizing, formulating and manufacturing any of our product candidates, and we currently lack the resources or capability to synthesize, formulate and manufacture any of our product candidates on a clinical or commercial scale. As a result, we will be dependent on third parties for the synthesis, formulation, manufacturing, including optimization, technology transfer and scale up, of clinical scale quantities of all of our product candidates. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing a manufacturing infrastructure.

Because we are focused on discovery and development of drugs, we do not have any marketing or distribution capabilities, nor are we at a stage where we would have any customers.

Competition

The development and commercialization of new drugs is highly competitive. We will face competition with respect to all product candidates we may develop or commercialize in the future from pharmaceutical and biotechnology companies worldwide. The key factors affecting the success of any approved product will be its efficacy, safety profile, drug interactions, method of administration, pricing, reimbursement and level of promotional activity relative to those of competing drugs. If approved, we would expect our clinical-stage product candidates and MRX-6, to compete with approved drugs and potentially with product candidates currently under development, including the following:

- MRX-6. If approved, we would expect MRX-6 to compete in the dermatitis drug market with skin ointments that contain steroids (Hydrocortisone®, Fluticasone®, Betamethasone®) and the drugs Elidel® and Protopic®, which are non-steroidal anti-inflammatory ointments. The leading companies in the market include Galderma, Medicis and Novartis (the manufacturer of Elidel®). According to GlobalData, the total volume of the market, as of its 2011 report, is approximately $2.4 billion, and is dominated mostly by steroidal ointments.

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

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

We believe that Anthera Pharmaceuticals, Inc. and Ziarco Pharma, Ltd., are the only other companies that were or are recently focused on the phospholipase A2 pathway like Celsus. Anthera is a biopharmaceutical company focused on developing and commercializing products to treat serious diseases, including cardiovascular and autoimmune diseases. It has in-licensed a portfolio of clinical and pre-clinical inhibitors of PLA2 and is developing an in-licensed drug from Eli Lilly and Shinogi & Co., which they developed as part of their collaboration. Anthera's drug candidates are entirely different in both structure (chemical class) and function to Celsus's product candidates. Ziarco Pharma, Ltd. is pursuing development of cytosolic PLA2 inhibitors, a different segment of the PLA2 pathway, and Ziarco's drug candidates are entirely different in both structure (chemical class) and function to Celsus's product candidates. Other companies, such as Anacor Pharmaceuticals, HanAll BioPharma Co., Ltd., PreCision Dermatology, Inc., Takeda, Otsuka, and Leo Pharma are pursuing other pathways and mechanisms to treat dermatitis.

Organizational Structure

Celsus Therapeutics Plc is organized under the laws of England and Wales and has two wholly-owned subsidiaries: Celsus Therapeutics Inc., a company incorporated under the laws of the State of Delaware, or Celsus USA, and Morria Biopharma Ltd., a company formed under the laws of Israel, or Morria Israel. Neither of these subsidiaries currently conduct any material business.

Corporate History

On November 27, 2002, Morria Biopharmaceuticals Inc., which changed its corporate name to Celsus Therapeutics, Inc., or Celsus USA, a Delaware corporation, entered into a license agreement with Yissum, the research and development arm of the Hebrew University, granting Celsus USA an exclusive, global license to develop Yissum's technology in the field of lipid conjugates that may halt and/or minimize the inflammatory process for the treatment of disease.

In January 28, 2005, Celsus USA and Morria Biopharmaceuticals Limited #5252842, a private limited liability company formed under the laws of England and Wales on October 7, 2004 (then known as "Freshname No. 333 Limited"), entered into a merger agreement. On January 19, 2005, "Freshname No. 333 Limited" changed its name to the name of "Morria Biopharmaceuticals Limited." On February 1, 2005, Celsus USA sublicensed, on a global and exclusive basis, the technology it licensed from Yissum to Morria to sell, market and distribute the licensed technology as defined in the original license agreement between Celsus USA and Yissum. On February 15, 2005, Morria re-registered as a non-traded public limited company under the laws of England and Wales in order to facilitate raising capital in the United Kingdom, under the name of Morria Biopharmaceuticals Plc.

On March 22, 2011, we incorporated an Israeli subsidiary, Morria Biopharma Ltd. #51-459419-1, or Morria Ltd. Morria Ltd. is fully owned by Morria. As of the date of this report, Morria Ltd. does not conduct any operations. In June 2013, we changed our corporate name to Celsus Therapeutics Plc.

Employees

As of December 31, 2014 we had five full time employees. As of December 31, 2013, we had four full-time employees. As of December 31, 2012, we had two full-time employees and one full-time employee. As of December 31, 2014, two employees were engaged in research and development and three employees were engaged in management, administration and finance. All employees are located in the United States.

None of our employees are members of labor unions.

Government Regulation

To date, we have conducted our pre-clinical and clinical trials in Israel and South Africa. We do not have the ability to independently conduct clinical trials for our product candidates, and we rely on third parties, such as contract research organizations, medical institutions, and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities. Although we have, in the ordinary course of business, entered into agreements with these third parties, we continue to be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA will require us 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 does not relieve us of these responsibilities and requirements. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them.

We plan to seek approvals in the European Union from the European Medicines Authority, or EMA, and in the United States from the Food and Drug Administration, or FDA. Therefore, we currently are and may be in the future subject to a variety of national and regional regulations governing clinical trials and commercial sales and distribution of our products, if any. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

We currently have all necessary approvals for the pre-clinical studies we conduct on animals in Israel. In order to conduct pre-clinical studies on animals in Israel, companies must obtain the approval of the Ministry of Health and the Council for Trials on Animals at the Ministry of Health, which operates pursuant to the Prevention of Cruelty to Animals Law (Experiments on Animals) 5754 — 1994. The approvals of the following committees are given on applications as they are submitted:

Institutional Review Board (IRB), also known as an Independent Ethics Committee (IEC) or Ethical Review Board (ERB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Helsinki (ethics) Committee — An Israeli Committee that acts according to the Public Health Regulations (Clinical Trials on Human Subjects) 1980, including all subsequent additions and amendments thereto until 1999 and applies the principles stated in the Helsinki and ICH-GCP Guidelines. The Committee deliberates on proposals for clinical trials on human subjects. It also deliberates on research proposals in the sphere of the social sciences. The Committee operates under the auspices of the Ministry of Health and the State Comptroller. The Committee is comprised of at least five (five to 11) members who have attained senior status in their professions and in academia.

Clinical trials in Israel must undergo inspection by and receive prior approval from an ethics committee at the institute at which the trial is to be conducted as well as from the Israeli Ministry of Health. In accordance with the Declaration of Helsinki, legislation developed by the World Medical Association as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data, the supervisory committee of the clinical trials at the institute at which the trial is conducted, or the Helsinki committees, and the relevant healthcare regulatory authority consider, when examining the application, among other things, the ethical foundations related to the trial, the safety of the product to the user and the exposure to tort claims of the institute conducting the trial. Results of pre-clinical trials, along with the details on the manner of manufacturing products and their analytic properties (i.e., composition, stability of the drug over time, etc.), are also examined as part of the approval process for conducting clinical trials on humans. We have received the approval of the Helsinki committees at Hadassah Ein-Kerem, Ichilov, where have conducted our Phase 1 and 2 trials, as well as the Israeli Ministry of Health.

United States

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our product candidates and commercialized drugs.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies, performed in accordance with the FDA's good laboratory practice, or GLP, regulations and other applicable requirements;
- submission to the FDA of an IND which must become effective before clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a New Drug Application, or NDA, to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, regulations;
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug; and
- regulation of commercial marketing and sale of drugs.

This testing and review process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of pre-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the clinical trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP regulations and regulations for informed consent.

Clinical Trials

For purposes of an NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap:

- *Phase 1:* The clinical trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. Phase 1 clinical trials can be designed to evaluate the impact of the product candidate in combination with currently approved drugs.
- *Phase 2:* These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trial.
- *Phase 3:* These clinical trials are commonly referred to as pivotal clinical trials. If the Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval.

New Drug Application

The results of product candidate development, pre-clinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators do. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require further testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved drugs which have been commercialized. The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

Fast Track Designation

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

If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated product candidate may also qualify for one or more of the following programs:

- *Priority Review.* Under FDA policies, a product candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the product candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. We cannot suggest or in any way guarantee that any of our product candidates will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately grant drug approval.
- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve product candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA. In rare instances the FDA may grant accelerated approval of an NDA based on Phase 2 data and require confirmatory Phase 3 studies to be conducted after approval and/or as a condition of maintaining approval. We can give no assurance that any of our drugs will be reviewed under such procedures.

When appropriate, we may attempt to seek fast track designation or accelerated approval for our product candidates. We cannot predict whether any of our product candidates will obtain a fast track or accelerated approval designation, or the ultimate impact, if any, of the fast track or the accelerated approval process on the timing or likelihood of FDA approval of any of our product candidates.

Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a product candidate is intended to treat a chronic disease, as is the case with some of our product candidates, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our product candidates on a timely basis, if at all. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our product candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Other regulatory requirements

Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

European Union

The European Medicines Agency, or EMA, is a decentralized agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union, as well as the protection and promotion of public health through the evaluation and supervision of medicines for human use.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Reimbursement

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

The passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under a new Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

It is not clear what long-term effect the MMA will have on the prices paid for currently approved drugs and the pricing options for future approved drugs. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate any policies for public or private payers, it is not clear what if any effect the research will have on the sales of our product candidates if any such product candidate or the condition that it is intended to treat is the subject of a study. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.

The Patient Protection and Affordable Care Act, the PPACA, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, is expected to have a significant impact on the health care industry. The PPACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the PPACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the PPACA on pharmaceutical companies because many of the PPACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. In addition, although the United States Supreme Court has upheld the constitutionality of most of the PPACA, some states have indicated that they intend not to implement certain sections of the PPACA and some members of the U.S. Congress are still working to repeal the PPACA. These challenges add to the uncertainty of the effects of the PPACA. While it is too early to predict all the specific effects of the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition in the future.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates.

The Company's Internet address is www.celsustx.com. The Company's annual reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge through the Investor Relations section of our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains an internet site that contains our public filings with the SEC and other information regarding the Company, at www.sec.gov. These reports and other information concerning the Company may also be accessed at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The contents of these websites are not incorporated into this Annual Report. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

Item 1A. RISK FACTORS

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

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

Risks Relating to Our Financial Position and Our Business

We anticipate that we will incur losses for the foreseeable future and we may never achieve or sustain profitability.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred losses of $9,648,000, $3,620,000 and $4,268,000 for the years ended December 31, 2014, 2013 and 2012, respectively. In addition, our accumulated deficit as of December 31, 2014 and December 31, 2013 was $30,190,000 and $20,542,000, respectively. We expect to continue to incur significant research and development and other significant operating expenses and capital expenditures, depending on available resources, and anticipate that we will continue to have significant expenses and losses in the foreseeable future as we:

- conduct our ongoing Phase 2 clinical program of MRX-6 for atopic dermatitis;
- conduct in the United States our Phase 2 clinical program of MRX-6 for atopic dermatitis under an FDA IND;
- conduct the synthesis, formulation, and manufacture of MRX-6;
- conduct pre-clinical toxicology and absorption, distribution, metabolism and excretion, or ADME, and stability studies for MRX-6;
- conduct pivotal toxicology studies for MRX-6;
- conduct the synthesis, formulation and manufacture of OPT-1;
- conduct pre-clinical toxicology and ADME, and stability studies for OPT-1;
- conduct pre-clinical studies of OPT-1 for allergic conjunctivitis or post-operative inflammation;
- conduct pre-clinical studies of CFX-1 for cystic fibrosis;
- conduct the synthesis, formulation and manufacture of CFX-1;
- conduct pre-clinical toxicology and ADME, and stability studies for CFX-1;
- conduct pre-clinical studies of OAX-1 in osteoarthritis;
- conduct the synthesis, formulation and manufacture of OAX-1;
- conduct pre-clinical toxicology and ADME, and stability studies for OAX-1;
- expand our management; and

- prepare and make filings with regulatory agencies, potentially including, but not limited to, IND filings with the FDA and clinical trial authorizations in one or more European countries for MRX-6 and potentially OPT-1, CFX-1, and OAX-1, a candidate for injection in osteoarthritis.

We must generate significant revenue to achieve and maintain profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or maintain profitability.

We are a development stage company and our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a development stage company. We commenced operations in February 2005. Our operations to date have been limited to organizing and staffing our company, acquiring, developing, and securing our technology, and undertaking pre-clinical studies and certain clinical trials of our product candidates. We have not filed New Drug Applications, or NDAs in the United States for our product candidates and we have not yet demonstrated an ability to obtain regulatory approval, or to synthesize, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or had previously discovered, developed, and/or commercialized an approved product.

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 our product candidates.

As of December 31, 2014, we had existing cash and investment securities of approximately $6.2 million. We will require additional capital in order to complete the clinical development of and to commercialize our product candidates and our pre-clinical product candidates and to expand our operational plan and management.

Our operating plan for fiscal year 2015 includes accounting, legal, personnel and corporate expenses to maintain our listing as a public company, as well as research and development expenses which includes personnel expenses, the synthesis, formulation and manufacturing work of MRX-6 for its Phase 2 and potentially Phase 3 clinical trials, conduct the MRX-6 Phase 2 program, and depending on available resources, develop our pipeline candidates. In February 2014, we received investments totaling approximately $9,200,000 that enabled us to continue the development of MRX-6, execute our Phase 2 trial and initiate additional research and development activities.

Our future capital requirements will depend on many factors that are currently unknown to us, including:

- clinical results for MRX-6;
- the timing and costs related to the filing of INDs for CFX-1, OPT-1 and OAX-1;
- the results of pre-clinical studies of OPT-1, CFX-1, and OAX-1 and the timing of initiation, progress, results and costs of any clinical trials that we may initiate based on the pre-clinical results;
- the costs of synthesis and formulation;
- the costs of raw materials in order to produce our product candidates;
- the costs of producing the product candidates;
- the costs of establishing commercial manufacturing arrangements and of establishing sales and marketing functions, if needed;
- the cost of 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.

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 clinical trials or other development for one or more of our product candidates.

We may seek to raise any necessary funds through public or private equity offerings, debt financings, 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.

Provisions in the investment agreements from our past financings may result in significant dilution for existing shareholders.

The securities purchase agreements from our private placement financings in November 2012 and January and February 2013 contained "down round" price protection provisions, which provide that until April 16, 2015, if we make certain dilutive issuances of ordinary shares at a price per ordinary share below the per share purchase price of $2.00 (referred to as a "dilutive issuance"), then immediately after such dilutive issuance, we will be obligated to issue to each purchaser, without the payment of additional consideration, additional ordinary shares, pursuant to the formula set forth in such securities purchase agreements. As a result of our September 2013 financing which had a per share purchase price of $0.57 per ordinary share, we issued additional shares to such purchasers. Accordingly, if we were to issue ordinary shares at less than $0.57 per ordinary share (subject to customary exceptions), we would be required to issue more additional shares to these purchasers. In addition, in the event we sell warrants or other rights (subject to customary exceptions) with an exercise price below $2.00 per ordinary share, the exercise price of the warrants issued in such financings shall be reduced to such lower exercise price. In addition, such securities purchase agreements also contained a most favored nations provision that provides the purchasers with the right to exchange their shares and warrants acquired in the financings for securities issued in a subsequent placement on a dollar for dollar basis in lieu of cash consideration. These same price protection provisions are also in the subscription agreements dated September 30, 2012, March 20, 2013, April 9, 2013, April 30, 2013, May 13, 2013, September 10, 2013 and September 17, 2013 relating to the purchase of an aggregate of 135,525 shares. The down round terms from these financings could result in significant and material dilution to current shareholders if we were to sell our ordinary shares at a price below $0.57 per ordinary share or issue warrants with an exercise price less than $2.00 per ordinary share.

Raising additional capital may cause dilution to existing shareholders, restrict our operations or require us to relinquish rights.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Capital markets have recently experienced a period of disruption and instability, which has had and could have a negative impact on the availability and cost of capital.

The United States capital markets had recently been adversely affected by economic problems experienced in the United States and abroad, particularly in Europe. These global conditions impacted the broader worldwide financial and credit markets and reduced the availability of debt and equity capital for the market as a whole. These global conditions could recur and persist for a prolonged period of time or worsen in the future. Our ability to access the capital markets may be restricted at a time when we would like, or need, to access those markets, which could have an impact on our flexibility to react to changing economic and business conditions. The resulting lack of available credit, lack of confidence in the financial sector, increased volatility in the financial markets could materially and adversely affect the cost of debt financing and the proceeds of equity financing may be materially adversely impacted by these market conditions.

Our future success depends on our ability to retain our key executives and to attract, retain, and motivate qualified personnel.

The competition for qualified personnel in the biopharmaceutical field is intense and we must retain and motivate highly qualified scientific personnel as well as attract new personnel. We are highly dependent on certain officers and employees, including Mr. Mark Cohen, our Executive Chairman, Dr. Gur Roshwalb, our Chief Executive Officer, Dov Elefant, our Chief Financial Officer and Dr. Pablo Jimenez, our Chief Medical Officer. All of the agreements with these principal members of our executive and scientific teams provide that employment is at-will and may be terminated by the employee at any time and without notice. The loss of the services of any of these persons might impede the achievement of our research, development, and commercialization objectives. Recruiting and retaining qualified scientific personnel and possibly sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. We do not maintain "key person" insurance on any of our employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We will need to hire additional employees in order to commercialize our product candidates in the future. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.

In order to commercialize our product candidates in the future, we will need to hire experienced sales and marketing personnel to sell and market those product candidates we decide to commercialize, and we will need to expand the number of our managerial, operational, financial and other employees to support commercialization. Competition exists for qualified personnel in the biopharmaceutical field.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are exposed to risks related to foreign currency exchange rates.

Some of our costs and expenses are denominated in foreign currencies. When the United States dollar weakens against the foreign currencies, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the foreign currencies, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

Our success is largely dependent on the success of our product candidates, and we cannot be certain that we will be able to obtain regulatory approval for or successfully commercialize any of these product candidates.

We have invested significant time and financial resources in the development of our product candidates. We anticipate that our success will depend largely on the receipt of regulatory approval and successful commercialization of our product candidates. The future success of our clinical and pre-clinical programs will depend on several factors, including the following:

- our ability to provide acceptable evidence of their safety and efficacy;
- receipt of marketing approval from the FDA and similar foreign regulatory authorities;
- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers or establishing commercial-scale manufacturing capabilities;
- possibly establishing an internal sales force or collaborating with pharmaceutical companies or contract sales organizations to market and sell any approved drug;
- acceptance of any approved drug in the medical community and by patients and third-party payers;
- the availability of the raw materials to produce our product candidates; and
- the ability to manufacture API and drug product in a timely manner that meets specifications such as stability; and
- the submission and approval of regulatory filings, and availability of Drug Master Files for raw materials that we are using.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenues through the license or sale of any of our product candidates.

Our product candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our product candidates, we will not be successful.

To date, we have not filed any US New Drug Applications, or NDAs, have not received regulatory approval, nor distributed or sold any drugs. The success of our business depends substantially upon our ability to develop, obtain approval for and commercialize our product candidates successfully. We currently have a clinical-stage product candidate in development, MRX-6, which is in the early stages of clinical development. Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of MRX-6 or any other product candidate for a target indication, we must demonstrate with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication. Our previous Phase 2 clinical trials of MRX-6 in contact dermatitis were conducted as academic studies and, thus, are neither International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, nor FDA-compliant. We are currently conducting an ICH compliant Phase 2 clinical trial of MRX-6 cream 2% in pediatric atopic dermatitis, but have no assurance of positive results. We will be required to execute further clinical trials that will be either FDA compliant or ICH compliant and, thus, compliant with the FDA's rules, in order to advance this product candidate's development and gain approval for marketing. We intend to continue to execute such trials in 2015, 2016 and 2017. We filed an IND for MRX-6 (for atopic dermatitis) in December 2014, which was allowed by the FDA in January 2015, and will potentially file INDs for OPT-1, CFX-1 and/or OAX-1 in 2016. We also plan, depending on available resources, to initiate pre-clinical work to advance OPT-1 for ophthalmologic indications, potentially CFX-1 in cystic fibrosis, and potentially OAX-1 in osteoarthritis in 2015. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. Despite our efforts, our product candidates may not:

- offer improvement over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- meet applicable regulatory standards; or
- be successfully commercialized.

Positive results in pre-clinical studies of a product candidate may not be predictive of similar results in humans during clinical trials, and promising results from early clinical trials of a product candidate may not be replicated in later clinical trials. Interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from completed pre-clinical studies and clinical trials for our product candidates may not be predictive of the results we may obtain in later stage trials or studies. Our pre-clinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional pre-clinical studies or clinical trials, or to discontinue clinical trials altogether. We may also decide to stop development of a product candidate for other reasons. We do not expect any of our product candidates to be commercially available for at least several years and some or all may never become commercially available.

If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials. A number of events, including any of the following, could 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 or any foreign regulatory authority regarding the scope or design of our clinical trials;
- the possible lack of acceptance of our data from our Phase 2 results by the FDA, due to the fact that the trials were not conducted under FDA good clinical practice requirements or in the United States;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates supply or materials to produce our product candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- serious and unexpected drug-related side effects experienced by patients in clinical trials;
- failure of our third-party contractors to meet their contractual obligations to us in a timely manner;
- pre-clinical or clinical trials may produce negative or inconclusive results, which may require us or any potential future collaborators to conduct additional pre-clinical or clinical testing or to abandon projects that we expect to be promising;
- even if pre-clinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require us to conduct unanticipated additional clinical trials;

- registration or enrollment in clinical trials may be slower than we anticipate, resulting in significant delays or study terminations;
- we or any potential future collaborators may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, other regulatory authorities or the IRBs at the sites where the IRBs are overseeing a trial due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- the imposition of a clinical hold by the FDA;
- varying interpretation of data by the FDA or similar foreign regulatory authorities;
- failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;
- seasonal issues, as the conducting of our clinical trials may be dependent on the season of the year;
- unforeseen safety issues; or
- the lack of adequate funding to continue the formulation, manufacture and/or clinical trials.

Additionally, changes in standard of care or regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Such amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial. Such changes may also require us to reassess the viability of the program in question.

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. In addition, if we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be affected and our ability to generate product revenues will be delayed. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Even if our product candidates receive regulatory approval in the United States, we may never receive 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 safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our product candidates and may have a material adverse effect on our results of operations and financial condition.

Both before and after marketing approval, our product candidates will be subject to ongoing regulatory requirements, and if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions and the sale of any approved commercial products could be suspended.

Both before and after regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product candidates are subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new product candidates or supplements to approved applications.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies.

In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. Even if we submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries.

If side effects emerge that can be linked to our product candidates are in development or after they are approved and on the market, we may be required to perform lengthy additional clinical trials, change the labeling of any such products, or withdraw such products from the market, any of which would hinder or preclude our ability to generate revenues.

If we identify side effects or other problems occur in future clinical trials, we may be required to terminate or delay clinical development of the product candidate. Furthermore, even if any of our product candidates receives marketing approval, as greater numbers of patients use a drug following its approval, if the incidence of side effects increases or if other problems are observed after approval that were not seen or anticipated during pre-approval clinical trials, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to reformulate such products, change the way the product is manufactured or administered, conduct additional clinical trials or change the labeling of the product;
- we may become the target of lawsuits, including class action suits; and
- our reputation in the market place may suffer resulting in a significant drop in the sales of the affected products.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

We have not conducted any absorption, distribution, metabolism and excretion (ADME), studies with respect to our clinical and pre-clinical product candidates.

To date, we have not conducted any ADME studies with respect to any of our product candidates as they were not required in order for us to carry out the studies done to date. The objective of the ADME studies is to determine if the test substance or any of its components are absorbed and if any absorbed components are metabolized into harmful chemicals that may or may not accumulate in the body. We will, however, be required to, and will conduct, ADME studies prior to final submission of our product candidates to the FDA and EMEA for drug approval. In the event that our ADME studies show detrimental effects on certain tissues or poor efficacy, we may be required to terminate or delay clinical development of a particular product candidate.

The number of subjects in our study pools in our clinical trials may be deemed by regulators to be too small.

Our clinical trials have been conducted on a pool of subjects that is structured for such research. Nevertheless, there is the possibility that for statistical reasons, the pool of subjects may be determined by the FDA or another regulatory body to be too small to verify statistical significance. In such a case, the conclusions from the previous trials will need to be established with at least another set of clinical trials testing the relevant issue.

While we choose to test our product candidates in specific clinical indications based in part on our understanding of their mechanisms of action, our understanding may be incorrect or incomplete and, therefore, our product candidates may not be effective against the diseases tested in our clinical trials.

Our rationale for selecting the particular therapeutic indications for each of our product candidates is based in part on our understanding of the mechanism of action of these product candidates. However, our understanding of the product candidate's mechanism of action may be incomplete or incorrect, or the mechanism may not be clinically relevant to the diseases treated. In such cases, our product candidates may prove to be ineffective in the clinical trials for treating those diseases.

We may not be able to keep up with the rapid technological change in the biotechnology and pharmaceutical industries, which could make any future approved products obsolete and reduce our revenue.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. In addition, any future products that we develop, including our clinical product candidates, may become obsolete before we recover expenses incurred in developing those products, which may require that we raise additional funds to continue our operations.

A successful sPLA2 drug has not been developed to date and we can provide no assurances that we will be successful or that there will be no adverse side effects.

Our unique lead product candidates are first-in-class, novel, non-steroidal, synthetic anti-inflammatory products that address the need to target sPLA2 in a broad-ranged manner while avoiding any interference with the homeostatic cPLA2 family. To date no drug companies have successfully developed an sPLA2 inhibitor and as a result the efficacy and long term side effects are not known. There is no guarantee that we will successfully develop an sPLA2 inhibitor or that the drug will have no adverse side effects.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives regulatory approval, if the approved product does not achieve broad market acceptance, the commercial success and revenues that we generate from sales of the product will be limited.

Even if product candidates we may develop or acquire in the future obtain regulatory approval, they may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues or receive royalties to the extent we currently anticipate, and we may not become profitable. The degree of market acceptance for any approved product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- prevalence and severity of adverse side effects;
- availability of reimbursement from government health programs and other third-party payers;
- convenience and ease of administration;
- cost-effectiveness;
- timing of market introduction of competitive products;
- ineffective marketing and distribution support of our products;
- potential advantages over alternative treatments;
- whether the products we commercialize remain a preferred course of treatment;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the cost of the materials to produce our product candidates;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If our approved product candidates fail to achieve broad market acceptance, we may not be able to generate significant revenue and our business would suffer. Furthermore, if any of these events were to occur and, as a result, we or any potential future collaborators have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would materially and adversely impact our business, financial condition and growth prospects.

If we or any potential future collaborators observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we or any potential future collaborators may be required to perform lengthy additional clinical trials, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

If the incidence of serious or other adverse events related to our product candidates increases in number or severity, if a regulatory authority believes that these or other events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we or any potential future collaborators may conduct in the future or after any of our product candidates are approved and marketed, then:

- we or any potential future collaborators may be required to conduct additional pre-clinical or clinical trials, make changes in the labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our contractors' manufacturing facilities;

- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;

- we may experience a significant drop in the sales of the affected products;

- our reputation in the marketplace may suffer; and

- we may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected product candidates or products, or could substantially increase the costs and expenses of commercializing and marketing any such products.

If we are unable to establish sales and marketing capabilities or enter into and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.

We do not currently have an organization nor have any experience in sales, marketing and distribution of pharmaceutical products. We will need to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates. In order to market any products that may be approved by the FDA, or similar foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities, license to a commercial partner, or make arrangements with third parties to perform these services. There are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates if approved for commercial sale. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and our business would suffer. In addition, to the extent that when we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we could market and sell any products that we develop ourselves.

If we and/or any potential future collaborators are unable to obtain reimbursement or experience a reduction in reimbursement from third-party payers for products we sell, our revenues and prospects for profitability will suffer.

Sales of products developed by us and/or any potential future collaborators are dependent on the availability and extent of reimbursement from third-party payers. Changes in the reimbursement policies of these third-party payers that result in reduction of reimbursements for our prospective product candidates and any other products that we and/or any potential future collaborators may develop and sell, could negatively impact our future operating and financial results.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established comprehensive Medicare coverage and reimbursement of prescription drugs under Medicare Part D. The prescription drug program established by this legislation may have the effect of reducing the prices that we or any potential future collaborators are able to charge for products we and/or any potential future collaborators develop and sell through the program. This legislation may also cause third-party payers other than the federal government, including the states under the Medicaid program, to discontinue coverage for products that we and/or any potential future collaborators may develop or to lower the amount that they pay.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.

The Patient Protection and Affordable Care Act, the PPACA, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, is expected to have a significant impact on the health care industry. The PPACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the PPACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the PPACA on pharmaceutical companies because many of the PPACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. In addition, although the United States Supreme Court has upheld the constitutionality of most of the PPACA, some states have indicated that they intend not to implement certain sections of the PPACA and some members of the U.S. Congress are still working to repeal the PPACA. These challenges add to the uncertainty of the effects of the PPACA. While it is too early to predict all the specific effects of the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition in the future.

Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization for use of drugs where supplemental rebates are not provided. Private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services, and many of these third-party payers may limit reimbursement for newly-approved health care products. In particular, third-party payers may limit the indications for which they will reimburse patients who use any products that we and/or any potential future collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Similar cost containment initiatives exist in countries outside of the United States, particularly in the countries of the European Union, where the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or any potential future collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or a potential future collaborators' commercialization efforts. Third-party payers are challenging the prices charged for medical products and services, and many third-party payers limit reimbursement for newly-approved health care products. In particular, third-party payers may limit the indications for which they will reimburse patients who use any products that we and/or any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us. Another development that could affect the pricing of drugs would be if the Secretary of Health and Human Services allowed drug re-importation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug re-importation into the United States under some circumstances from foreign countries, including from countries where the drugs are sold at a lower price than in the United States. If the circumstances were met and the Secretary exercised the discretion to allow for the direct re-importation of drugs, it could decrease the price we or any potential future collaborators receive for any products that we and/or any potential future collaborators may develop, negatively affecting our revenues and prospects for profitability.

If we are unable to establish manufacturing capabilities or enter into agreements with third parties to supply materials to make our product candidates, or manufacture our clinical trial drug supplies, we may be unable to generate product revenue.

We do not currently have the capability to manufacture pharmaceutical products. In order to commercialize any products that may be approved by the FDA, or similar foreign regulatory authorities, we must build and operate manufacturing, storage and distribution facilities, or make arrangements with third parties to perform these services. If we are unable to establish manufacturing capabilities, whether independently or with third parties, we may not be able to generate product revenue and our business would suffer.

Changes in healthcare policy could adversely affect our business.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drugs purchased by Medicare beneficiaries and introduced new reimbursement methodologies. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. We do not know what impact the MMA and similar laws will have on the availability of coverage for and the price that we receive for any approved products. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare policies in setting their own reimbursement policies, and any reduction in reimbursement that results from the MMA may result in similar reductions by private payers.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.

The Patient Protection and Affordable Care Act, the PPACA, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, is expected to have a significant impact on the health care industry. The PPACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the PPACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the PPACA on pharmaceutical companies because many of the PPACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. In addition, although the United States Supreme Court has upheld the constitutionality of most of the PPACA, some states have indicated that they intend not to implement certain sections of the PPACA and some members of the U.S. Congress are still working to repeal the PPACA. These challenges add to the uncertainty of the effects of the PPACA. While it is too early to predict all the specific effects of the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition in the future.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could incur substantial liability.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any approved product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to successfully commercialize any approved product candidates.

We obtained product liability insurance coverage for our clinical trials with $3 – $5 million of coverage for dermatitis clinical trials. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, and state gift ban laws which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

A federal law commonly known as the federal anti-kickback law, and several similar state and foreign laws, prohibit the payment of any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. Other federal and state and foreign laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professional and health care organizations. Some state statutes impose an outright ban on gifts to physicians. These laws are often referred to as "gift ban" or "aggregate spend" laws, and they carry substantial fines if they are violated. In addition, the ACA requires the annual reporting of certain payments and other transfers of value that are made to health care professionals in 2012 and thereafter. The federal ACA does not preempt all aspects of the similar state laws.

In the event that we are found to have violated these laws or decide to settle a claim that we have done so, our business may be materially adversely affected as a result of any payments required to be made, restrictions on our future operations or actions required to be taken, damage to our business reputation or adverse publicity in connection with such a finding or settlement or other adverse effects relating thereto. Additionally, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

If our competitors are better able to develop and market products than any products that we and/or any potential future collaborators may develop, our commercial opportunity will be reduced or eliminated.

We face competition from commercial pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or any potential future collaborators may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenue and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting in our pipeline and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish any ability to market and sell any products that we and/or any potential future collaborators may develop.

With respect to our clinical and pre-clinical programs, there are other product candidates in development that may compete with our product candidates and any future similar product candidates, if approved for commercial sale. Our closest competitor of which we are aware is Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH), which was actively developing a PLA2 inhibitor treatment of cardiovascular disease in phase 3 clinical trials, although these trials were stopped due to lack of efficacy, and Ziarco Pharma, Ltd, which is developing a cytosolic PLA2 inhibitor potentially for skin and lung diseases. Other competitors include Anacor Pharmaceuticals, as an example, which is pursuing the development of a boron based topical PDE-4 inhibitor for inflammatory skin disease. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Risks Related to Our Dependence on Third Parties

If we do not establish collaborations for our product candidates or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses. Our strategy includes selectively partnering or collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our product candidates in some or all geographies. We face significant competition in seeking appropriate collaborators, and collaborations are complex and time consuming to negotiate and document. We may not be successful in entering into new collaborations with third parties on acceptable terms, or at all, including as a result of the collaboration discussions we are pursuing for several of our product candidates. In addition, we are unable to predict when, if ever, we will enter into any additional collaborative arrangements because of the numerous risks and uncertainties associated with establishing such arrangements. If we are unable to negotiate new collaborations, we may have to curtail the development of a particular product candidate, reduce, delay, or terminate its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to raise substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenues.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality, and delivery schedules. We cannot be certain that our current suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are several other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, or interrupt production of the existing products that are already marketed, which would have a material adverse effect on our business.

Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaboration arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

In the future, we may not be able to locate third-party collaborators to develop and market our product candidates, and we may lack the capital and resources necessary to develop our product candidates alone. Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to our product candidates;
- potential future collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

If third parties do not manufacture our product candidates in sufficient quantities, in the required timeframe, and at an acceptable cost, clinical development and commercialization of our product candidates would be delayed.

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins, if any, and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We rely on third-party vendors for the manufacture of our materials. If our supply of these synthetic raw materials becomes unusable or if the contract manufacturers that we are currently utilizing to meet our supply needs for these materials or any future such product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional clinical trials of our product candidates or any future product candidates. Furthermore, the respective third parties hold the Drug Master File (DMF) on these materials. Accordingly, we will need to maintain access to them or create them ourselves, a procedure that will be very costly, and shall take time. In addition, we rely on third-party contractors for the manufacture of our drug substance. We currently rely on a sole supplier for the manufacture of our drug substance, our sole supplier may fail to manufacture an adequate supply of our drug substance or there may be manufacturing discrepancies in our drug substance, which could harm our business. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements as our manufacturing processes are not manufacturer specific, we may incur added costs and delays in identifying and qualifying any such replacements because the FDA must approve any replacement manufacturer prior to manufacturing our product candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of FDA approval.

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our product candidates.

To date, our product candidates have been manufactured in small quantities for pre-clinical testing and clinical trials by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If they are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates or products.

Reliance on third-party manufacturers entails risks, to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- drug product supplies not meeting the requisite requirements for clinical trial use.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

Although our present manufactures are in compliance with current FDA-mandated Good Manufacturing Practice regulations, there is no assurance that future manufacturing partners may be able to comply with those regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such clinical trials.

We do not have the ability to independently conduct clinical trials for our product candidates, and we rely on third parties, such as contract research organizations, medical institutions, and clinical investigators to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with these third parties, we continue to be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us 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 does not relieve us of these responsibilities and requirements. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

Risks Related to Our Intellectual Property

If we are unable to adequately protect the intellectual property relating to our product candidates, or if we infringe the rights of others, our ability to successfully commercialize our product candidates will be harmed.

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in scientific journals or patent literature, often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our product candidates or their use as drugs. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference or derivation proceedings declared at the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our products or by covering similar technologies.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing a less burdensome pathway to approval.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

We own or have exclusive rights to 24 United States and 21 foreign issued patents and allowed patent applications, and 11 United States and 49 foreign pending patent applications, as well as two (2) pending international patent applications. Issued patents which cover our product candidates MRX-6, OPT-1, CFX-1 and OAX-1 in the United States, will expire between 2021 and 2022, depending on the specific product candidates. Issued patents directed to our product candidates, MRX-6, OPT-1, CFX-1 and OAX-1 outside of the United States, will expire in 2021. We have pending patent applications for formulations of our product candidates , MRX-6, OPT-1, CFX-1 and OAX-1 that, if issued, would expire in the United States and in countries outside of the United States between 2021 and 2032, depending on the specific compositions and formulations: contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), cystic fibrosis (CFX-1) and osteoarthritis (OAX-1). We have an issued patent directed to methods of manufacturing which covers our product candidate compounds in the United States and which will expire in 2021. Issued patents directed to methods of treatment using our product candidates, MRX-6 and OPT-1 in the United States, will expire between 2021 and 2024, depending on the specific indication: contact dermatitis (MRX-6), conjunctivitis (OPT-1). Issued patents directed to use of our product candidate: MRX-6, OPT-1 and CFX-1 for indications outside of the United States, will expire between 2021 and 2026, depending on the specific indication: contact dermatitis (MRX-6), conjunctivitis (OPT-1), and cystic fibrosis (CFX-1). We have pending patent applications for use of our product candidates MRX-6, OPT-1, CFX-1 and OAX-1 that, if issued, would expire in the United States and in countries outside of the United States between 2021 and 2032, depending on the specific indications and formulations: contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), cystic fibrosis (CFX-1) and osteoarthritis (OAX-1).

We license patent rights from third-party owners. Our licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties. If we lose our license from Yissum we may be unable to continue a substantial part of our business.

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for a substantial part of our business. Pursuant to our exclusive license agreement with Yissum Research Development Company of the Hebrew University of Jerusalem, or Yissum, under which we license certain patent rights for our product candidates and their uses, we are required to use commercially reasonable best efforts to commercialize products based on the licensed rights and pay certain royalties and sublicensing revenue to Yissum. We may also enter into additional licenses to third-party intellectual property in the future. Our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Under our existing license agreements, we are obligated to pay the licensor fees, which include royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under our existing license agreements, we are required to use our commercially reasonable best efforts to pursue the development of products using the licensed technology. If we breach any of the terms of our Yissum license, Yissum may terminate the agreements prior to their expiration date of the term of the last to expire licensed patent, which would have a material adverse effect on our business.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our product candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Owning Our ADSs

If we are deemed or become a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2014 or in any prior or subsequent years, there may be negative tax consequences for U.S. taxpayers that are holders of our ADSs.

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

We believe that we will not be treated as a PFIC for U.S. federal income tax purposes 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. However, we do not currently intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we were treated as a PFIC for any taxable year.

A very 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 on January 31, 2014. 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;
- 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.

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 February 11, 2015, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 6.3% of our outstanding Ordinary Shares. These shareholders, if acting together, 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, acting together, 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.

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 2013 (included in our Annual Report on Form 20-F), which is 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 2014. 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.

Effective January 1, 2015, we lost our foreign private issuer status, which will result in significant additional costs and expenses.

Before January 1, 2015, we were a "foreign private issuer," as such term is defined in Rule 405 under the U.S. Securities Act of 1933, as amended. As such, we were exempt from certain provisions applicable to U.S. public companies including:

- the rules under the Securities Exchange Act of 1934, as amended, or Exchange Act, requiring the filing with the SEC of quarterly reports on Form 10-Q and current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information; and
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and establishing insider liability for profits realized from any "short-swing" trading transaction (a purchase and sale, or sale and purchase, of the issuer's equity securities within less than six months).

A foreign private issuer may lose this status if a majority of its directors are U.S. citizens or residents and it fails to meet additional requirements. We conducted the test for whether or not we are able to remain a foreign private issuer on June 30, 2014, and we determined that we would lose our status as a foreign private issuer effective as of January 1, 2015.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than costs we incur as a foreign private issuer. In addition to having to make the above described filings with the U.S. Securities and Exchange Commission, which are more detailed than forms typically filed by foreign private issuer, we will lose our ability to rely upon exemptions from certain corporate governance requirements and we will be required to prepare our financial statements in accordance with U.S. generally accepted accounting principles.

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

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

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

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

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

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

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

- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We do not own any property or fixed assets in our London office. We currently lease 4,900 square feet of office space in New York for approximately $24,000 per month. The lease terminates on August 31, 2019. We also lease office space and receive office services in London from a third party, which includes mail management and transfer, fax and telephone services and secretarial services for £345 (or approximately $500, based on an exchange rate as of February 11, 2015) (excluding VAT) per month. Each party may terminate this arrangement by giving three months' advance notice.

Item 3. LEGAL PROCEEDINGS

We are not involved in any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our ADSs have been listed on the NASDAQ Capital Market under the symbol "CLTX" since January 31, 2014. Prior to that, our ADSs were quoted on the OTCQB under the symbol "CLSXD" from January 3, 2014 to January 30, 2014 and were quoted on the OTCQB under the symbol "CLSXY" from September 16, 2013 until January 2, 2014 and under the symbol "MRRBY" from February 19, 2013 to September 15, 2013. Effective January 3, 2014, our ratio of ADS to ordinary shares changed from one ADS per each two ordinary shares to one ADS per each ten ordinary shares. Currently, each ADS is represented by ten ordinary shares.

The following table sets forth the range of high and low closing sale prices for our ADSs for the periods indicated, as reported by the NASDAQ Capital Market or the OTCQB, as applicable. These prices do not include retail mark-ups, markdowns, or commissions but give effect to the change in the number of ordinary shares represented by each ADS to ten ordinary shares per each ADS, implemented on January 3, 2014. Historical data in the table has been restated to take into account these changes.

	USD High	USD Low
Fiscal Year Ended December 31, 2013		
First Quarter	$ 25.00	$ 25.00
Second Quarter	$ 25.00	$ 20.00
Third Quarter	$ 20.00	$ 20.00
Fourth Quarter	$ 20.00	$ 7.10
Fiscal Year Ended December 31, 2014		
First Quarter	$ 11.00	$ 6.15
Second Quarter	$ 6.96	$ 5.00
Third Quarter	$ 6.27	$ 5.40
Fourth Quarter	$ 6.05	$ 4.70

From the date that our ADSs were first quoted on the OTCQB on February 19, 2013 to the date that our ADSs commenced trading on the NASDAQ Capital Market, a small number of ADSs traded at prices ranging from $7.10 to $25.00 per ADS (giving effect to the ADS ratio change effective January 3, 2014), as more fully described below:

- During the quarter ended March 31, 2013, a total of 60 ADSs were traded at a price of $25.00 per ADS.
- From April 1, 2013 to June 30, 2013, a total of 160 ADSs were traded at prices ranging from $20.00 per ADS to $25.00 per ADS.
- From July 1, 2013 to September 30, 2013, a total of 100 ADSs were traded at $20.00 per ADS.
- From October 1, 2013 to December 31, 2013, a total of 3,420 ADSs were traded at prices ranging from $7.10 per ADS to $20.00 per ADS.

Shareholders

As of February 11, 2015, there were 336 holders of record of our ordinary shares. Because many ordinary shares are held by broker nominees, we are unable to estimate the total number of shareholders represented by these record holders. Our depositary, Deutsche Bank Trust Company Americas, constitutes a single record holder of our ordinary shares.

Dividends

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

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,991,690	$ 1.41	2,873,310
Equity compensation plans not approved by security holders	—	—	—
Total	2,991,690	$ 1.41	2,873,310

2014 Plan

In order to retain qualified individuals, the Board previously established the 2007 Stock Option Plan The Company currently has issued Options representing 2,686,690 Ordinary Shares under the 2007 Stock Option Plan.

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

The option plan is administered by our board of directors and grants are made pursuant thereto by the Compensation Committee. The aggregate number of Ordinary Shares that may be issued upon exercise of options under the 2014 Plan shall be the sum of: (i) 3,033,310 Ordinary Shares and (ii) any Ordinary Shares that are represented by awards granted under the Company's 2007 Stock Option Plan that are forfeited, expire or are cancelled without delivery of Ordinary Shares or which result in the forfeiture of Ordinary Shares back to the Company on or after June 19, 2014, or the equivalent of such number of Ordinary Shares after the administrator, in its sole discretion, has interpreted the effect of any stock split, stock dividend, combination, recapitalization or similar transaction in accordance with the 2014 Plan; provided, however, that no more than 2,831,690 Ordinary Shares shall be added to the 2014 Plan pursuant to subsection (ii). Options may be granted at any time. As of February 11, 2015, options to purchase 305,000 of our Ordinary Shares were outstanding under the 2014 Plan. Unless sooner terminated, the Plan shall expire on April 30, 2024.

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

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

2007 Stock Option Plan

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

The option plan is administered by our board of directors and grants are made pursuant thereto by the Compensation Committee. The aggregate number of Ordinary Shares that may be issued upon exercise of options under the 2007 Stock Option Plan shall not exceed 3,865,000 Ordinary Shares. Our board of directors may, at any time during the term of the 2007 Stock Option Plan, increase the number of shares available for grant under the 2007 Stock Option Plan. Options may be granted at any time. As of February 11, 2015, options to purchase 2,686,690 of our Ordinary Shares were outstanding under the 2007 Stock Option Plan. Unless sooner terminated, the Plan shall expire on the tenth anniversary of its effective date, or August 28, 2017.

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

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

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

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

Item 6. SELECTED FINANCIAL DATA

Not required as we are a smaller reporting company.

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

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

Overview

We are a biopharmaceutical company dedicated to the discovery and development of novel, first-in-class, non-steroidal, synthetic anti-inflammatory drugs. We believe that we have developed a new class of synthetic drugs for therapeutic purposes that we term Multifunctional Anti-Inflammatory Drugs, representing a new multi-drug platform for the treatment of a wide range of inflammatory diseases and conditions. For decades, steroids have been the most commonly used anti-inflammatory drugs in the world, used extensively to treat inflammatory diseases and allergies. However, steroids are associated with severe side effects, such as metabolic changes, weight gain, changes in blood pressure, diabetes, cataract and glaucoma, psychosis and depression. These side effects have led to reluctance by both medical providers and their patients to use these drugs, providing an unmet need in multiple disease markets for safer alternatives to steroids.

The technology for Celsus's product candidates is based on research conducted by Prof. Saul Yedgar at the Hebrew University in Jerusalem, Israel. On November 27, 2002, Celsus Biopharmaceuticals Inc., or Celsus USA, a Delaware corporation, entered into a license agreement with Yissum, the research and development arm of the Hebrew University, granting Celsus USA an exclusive, global license to develop Yissum's technology in the field of lipid conjugates that may halt and/or minimize the inflammatory process for the treatment of disease.

Our lead clinical product candidate in Phase 2 development is MRX-6, a topical cream intended for treating atopic dermatitis, a common type of eczema. We also intend to undertake, depending on available resources, pre-clinical studies for other product candidates: OPT-1 for the treatment of conjunctivitis, post-operative inflammation and/or dry eye; CFX-1 for the treatment of cystic fibrosis; OAX-1 for the treatment of osteoarthritis and other inflammatory diseases. Given the common biochemical mechanism of all inflammatory diseases, we plan to gradually expand the application of our technology for our product candidates to other forms of inflammatory diseases in the future, such as, eosinophilic esophagitis, nasal polyps, etc.

We have completed first-in-patient clinical trials (Phase 2) of our lead product candidate MRX-6, a topical cream for atopic dermatitis, in Israel. We are currently conducting a double-blind, parallel-group, vehicle-controlled trial to evaluate the safety and efficacy of MRX-6 cream 2% in a pediatric population with mild to moderate atopic dermatitis. This trial randomized 74 patients into a four-week double-blind period, followed by a four-week open label extension for those patients who wish to continue in the trial. We anticipate completing the double-blind portion of this Phase 2 MRX-6 cream 2% clinical trial by end of February 2015. We submitted our IND for MRX-6 cream 2% to the FDA in December 2014, and announced FDA allowance of our IND in January 2014. We potentially also plan to submit an IND to the FDA for OPT-1, CFX-1, and/or OAX-1 in 2015 or 2016. If these applications are approved, we intend to seek licensing arrangements with international pharmaceutical companies.

We also intend to undertake, depending on available resources, pre-clinical studies for the development of drugs for inflammatory eye diseases, OPT-1; cystic fibrosis, CFX-1; osteoarthritis, OAX-1 and other inflammatory conditions. We intend to conduct such studies throughout 2015. OPT-1 pre-clinical studies planned to take place during 2015 include synthesizing and formulating the drug, conducting safety studies and animal models. CFX-1 pre-clinical studies are intended to be initiated in the first half of 2015, in which we intend to synthesize and formulate the drug, conduct safety studies and animal models. OAX-1 pre-clinical studies planned to take place during 2015 include synthesizing and formulating the drug, conducting safety studies and animal models. These studies will continue throughout 2015.

Our research and development expenses consist primarily of salaries and related 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 expense 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. Our board of directors, which consists of recognized professionals in the fields of biology, medicine and finance, regularly approves our material contracts with subcontractors.

Since inception in 2005, we have generated significant losses in connection with our research and development, including the pre-clinical and clinical development of our product candidates. At December 31, 2014, we had an accumulated deficit of $30,190,000. We have not yet generated any revenues and we expect to continue to generate losses in connection with the research and development activities relating to our pipeline of product candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we may continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further develop our research and development programs.

Since inception, we have funded our operations primarily through the sale of equity securities and equity-linked securities.

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 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. 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, "Compensation — Stock Compensation," 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 British government bond and 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.

In 2012 and 2013, our shares were not traded in an active market, and we had to determine our ordinary share fair value as part of the estimation process of our stock based compensation awards. The generally accepted approaches to valuation are commonly referred to market approach, discounted cash flows and asset-based approach. Since an intangible asset comprises our core value, the relevance of the asset approach tends to diminish significantly, and it will likely be more reliable to measure the value of intangible assets in aggregate through the use of an income or market approach method. We currently have substantive expense history, because product development is under way and we do not have product revenue. At this stage, we still have significant difficulty to project expected discounted cash flows and therefore we did not use the discounted cash-flow approach.

In determining the valuations of our Ordinary Shares prior to being a public traded company, we also considered the guidelines outlined in the "American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation." The assumptions we use in the valuation model are based on future expectations combined with management's judgment. In the absence of a public trading market, our management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our Ordinary Shares as of each date of measurement of our options, warrants and deferred shares, including the following factors: arm's length private transactions involving our stock, our operating and financial performance, market conditions, developmental milestones achieved, business risks, and management and board experience.

Consequently, in determining the Ordinary Share value in 2012 and 2013, we applied the market approach taking into account our actual equity transactions. In 2013, the value ranged between $0.57 – $1.73. In 2012, the value ranged from $1.54 – $1.72. Considering that the equity transactions through September 17, 2013 included warrant coverage, and the warrants and shares held anti-dilution rights, we isolated the stand-alone value of the common share by subtracting the value of the warrants and anti-dilution rights by performing numerous iterations in the Black Scholes option-pricing model. The major assumptions used for the valuation were the expected life of the options considering the company's stage of development, the volatility that was based comparable companies, and risk-free interest rate based on the yield of U.S. Treasury bonds. All financings in 2014 did not include any warrant coverage.

We listed our securities on the NASDAQ Capital Market in January 2014. As of December 31, 2014, the value was $0.48 and ranged between $0.48 – $0.65 in 2014.

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

Convertible Notes and Warrants

In connection with the April 2012 Financing, 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 detachable 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 operations as financial income or expense. The fair value of Warrants granted was valued by using the Black-Scholes call option pricing. The anti-dilution rights of the Warrants were calculated by using Black-Scholes 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 initial fair value of the detachable warrant on April 4, 2012 was $750,000. On December 31, 2012, the fair value of the detachable warrant was $402,000. The change in fair value in the amount of $348 was recognized as financial expense in the statement of operations. On December 31, 2013, the fair value of the detachable warrant was $424,000. The change in fair value in the year ended December 31, 2013 in the amount of $22,000 was recognized as financial expense in the statement of operations. On December 31, 2014, the fair value of the detachable warrant was $64,000. The change in fair value in the year ended December 31, 2014 was a decrease of $360 and was recognized as financial income in the statement of operations.

The conversion feature was not defined as a derivative instrument according to ASC 815, "Derivatives and Hedging" ("ASC 815") since our shares were not traded on the commitment date. We recognized the embedded beneficial conversion feature on the commitment date, in accordance with the guidelines of ASC 470-20. The beneficial conversion feature was measured by allocating a portion of the proceeds equal to the intrinsic value of the feature to additional paid-in-capital. The intrinsic value of the feature was calculated on the commitment date using the effective conversion price which had resulted subsequent to the allocation of the proceeds between the Notes and warrants. On the commitment date, we recorded a beneficial conversion feature in the amount of $250,000, in accordance with Statement of Accounting Standard Codification No. 470-20. The notes were repaid in January 2013, before our shares were traded and the conversion feature was qualified as a derivative according to ASC 815, therefore we were not required to re-measure the conversion feature as a liability related to warrants due to the "full ratchet" anti-dilution adjustments.

In relation to the issuances of August 2012 financing through September 17, 2013 financings, the Company first allocated the proceeds to the detachable warrant, that due to the most favored nation terms and in accordance with ASC 815 is being considered 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 statement of comprehensive loss as financial income or expense. The remaining proceeds were allocated to the shares and were recorded to equity. The issuance costs were allocated between the warrants and the shares in proportion to the allocation of the proceeds. The portion of the issuance costs that were allocated to the warrants was recorded as financial expense in the Company's statement of comprehensive loss. The portion of the issuance costs that were allocated to the shares was recorded to additional paid in capital.

The fair value of warrants granted was valued by using the Black-Scholes call option pricing model. The anti-dilution adjustments of most favored nation terms were calculated using Black-Scholes put option model since it's similar to put options by providing a guaranteed price for an underlying instrument and offer insurance against dilution. The Company used different parameters for the warrants call option and the warrants put option since the expected life of the most favored nation terms was shorter than the expected life of the warrants.

In addition, in relation to the 2013 financings, we allocated the proceeds to the detachable warrants, due to the most favored nation terms, with changes in the fair values being recognized in the Company's statement of comprehensive loss as financial income or expense. The initial value of all the 2013 warrants totaled approximately $471 and the value as of December 31, 2013 was $235. $217 was recorded as financial income for the year ended December 31, 2013. The value as of December 31, 2014 was $80. $155 was recorded as financial income for the year ended December 31, 2014.

Functional Currency

The Company's costs and financing are in U.S. dollars ("Dollar"). The Company's management believes that the Dollar is the currency of the primary economic environment in which the Company and its subsidiaries have operated and expect to continue to operate in the foreseeable future. Therefore, the functional currency of the Company and its subsidiaries is the Dollar.

Results of Operations

For the years ended December 31, 2014 and December 31, 2013

Research and development expenses

Research and development expenses for the year ended December 31, 2014 were approximately $6,417,000 compared to $1,276,000 for the year ended December 31, 2013. This 403% or $5,141,000 increase was due to higher expenses of approximately $4,889,000 for formulation and synthesis activities, manufacturing and clinical trials $99,000 of salary expenses, $54,000 of insurance expenses, $43,000 of travel related expenses, $25,000 of stock-based compensation expenses and $31,000 of other miscellaneous expenses.

Provided that we are able to raise additional capital, we expect our research and development expenses will increase over the next several years as we conduct additional clinical trials to support the clinical development of MRX-6, and advance other product candidates into pre-clinical and clinical development.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2014 were approximately $3,760,000 compared to $2,330,000 for the year ended December 31, 2013. This 61% or $1,430,000 increase was primarily due to higher legal, consulting, professional and accounting expenses of approximately $615,000, $294,000 from stock-based compensation expense related to options granted to board members and employees, $169,000 of board fees, $145,000 for office rent expenses, $111,000 for insurance, $56,000 from stock-based compensation expense related to shares granted to consultants, $47,000 of travel related expenses, and $42,000 for other general expenses offset by $49,000 of lower salaries.

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

Financial income/expenses

Financial income for the year ended December 31, 2014 was approximately $529,000 compared to financial expense of $14,000 for the year ended December 31, 2013. This change was primarily attributed to the revaluation of the warrant liabilities and amortization of convertible notes' discount.

For the years ended December 31, 2013 and December 31, 2012

Research and development expenses

Research and development expenses for the year ended December 31, 2013 were approximately $1,276,000 compared to $1,483,000 for the year ended December 31, 2012. This 13% or $207,000 decrease was due to lower expenses of approximately $240,000 for formulation and synthesis activities, manufacturing and clinical trials, $16,000 of stock-based compensation expenses and $3,000 for miscellaneous expenses, offset by higher expenses of $52,000 for salaries and benefits.

Provided that we are able to raise additional capital, we expect our research and development expenses will increase over the next several years as we conduct additional clinical trials to support the clinical development of MRX-6, and advance other product candidates into pre-clinical and clinical development. Without additional capital, we will not be able to perform research and development activities with respect to our product candidates.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2013 were approximately $2,330,000 compared to $2,184,000 for the year ended December 31, 2012. This 6% or $146,000 increase was primarily due to higher expenses of approximately $486,000 for salaries and benefits, $88,000 for insurance, $50,000 for board fees and $10,000 of other miscellaneous expenses offset by lower expenses of $377,000 of stock-based compensation expense related to options granted to employees, board members and consultants and $111,000 for legal, accounting and professional fees.

We expect our general and administrative expenses to increase due to increased compensation, legal, accounting and professional fees associated with being a public reporting company in the United States.

Financial income/expenses

Financial expenses for the year ended December 31, 2013 was approximately $14,000 compared to $601,000 for the year ended December 31, 2012. This change was primarily attributed to $697,000 of lower interest expense, offset by higher expense for the revaluation of the warrant liabilities of $51,000 and British Pound and US Dollar exchange rate differences and bank fees of $59,000 due to the year-end exchange rates were different than the average rates during the year.

Liquidity and Capital Resources

Net cash used in operating activities was approximately $9,461,000 during the year ended December 31, 2014 compared to $5,450,000 used by operating activities during the year ended December 31, 2013. The 74% increase in cash flow used in operating activities of approximately $4,011,000 can be primarily attributed to the initiation of additional formulation, manufacturing and clinical trial activities.

Net cash used in financing activities was approximately $199,000 during the year ended December 31, 2014 and was attributed to purchase of furniture and equipment and investment in short term restricted deposit. In 2013 we had no investment activity. We anticipate our investment will be minimal in the future.

Net cash provided by financing activities was approximately $8,219,000 during the year ended December 31, 2014 compared to approximately $12,003,000 during the year ended December 31, 2013. Financing activities in fiscal 2014 and 2013 were comprised of cash proceeds from the issuance of shares and warrants offset by the repayment of the convertible notes in 2013.

As of December 31, 2014, we had approximately $6,216,000 in cash and cash equivalents, a decrease of approximately $1,441,000 from December 31, 2013. In addition, as of December 31, 2014, we had accumulated losses in the total amount of approximately $30,190,000.

Since inception, we have funded our operations primarily through the sale of equity securities and equity-linked securities. In the months of January through November 2012, we sold Ordinary Shares for net proceeds of approximately $2,448,000. Furthermore, in April 2012, we completed a private placement in which we sold an aggregate of $1,100,000 principal amount of convertible notes for net proceeds of $1,000,000 (which was repaid on January 2, 2013), and in November 2012, we completed a private placement in which we sold an aggregate 751,500 Ordinary Shares for net proceeds of $1,503,000. From January 2013 through September 17, 2013, we raised an aggregate of approximately $1,706,300 in private placements of ordinary shares and warrants. On September 24, 2013, we completed a private placement with certain institutional accredited investors in which we sold an aggregate of 21,958,302 ordinary shares for an aggregate purchase price of $12,516,232. Subsequent to the September Financing, we used the proceeds to initiate product development activities and paid certain outstanding payables that were delayed as the Company awaited the completion of its financing. In February 2014, we completed a public offering of 1,533,333 ADSs for gross proceeds of approximately $9,200,000. As of December 31, 2014, we have existing cash and investment securities of approximately $6.2 million.

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

- the timing of initiation, progress, results and costs of our clinical trials for MRX-6; the timing and costs related to the filing of INDs for CFX-1, OAX-1 and OPT-1; the results of pre-clinical studies of OPT-1, CFX-1, and OAX-1 and the timing of initiation, progress, results and costs of any clinical trials that we may initiate based on the pre-clinical results;
- the costs of synthesis and formulation;
- the costs of raw materials in order to produce our product candidates;
- the costs of producing the product candidates;
- the costs of establishing commercial manufacturing arrangements and of establishing sales and marketing functions, if needed;
- 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.

Pursuant to the terms of the 2013 Financing warrants, we may raise additional capital upon terms no more favorable to the new investors than those offered to such investors. In addition, if we make certain dilutive issuances, the exercise price of the warrants will be lowered to the per share price paid in the applicable dilutive issuance. Such terms and conditions may make it more difficult to raise additional capital on terms favorable to us.

Research and Development, Patents and Licenses

Our research and development expenditures were $6,417,000 and $1,276,000 in the years ended December 31, 2014 and 2013, respectively. Most of such research and development expenditures were in the form of payments to third parties to carry out our formulation and synthesis activities, manufacturing, pre-clinical and clinical research activities.

We incurred the following research and development expenses in the years ended 2014 and 2013:

	Years ended December 31,	
	2014	2013
Direct Expenses:		
MRX-6	$ 5,750	$ 245
Other	—	589
Total direct expenses	$ 5,750	$ 834
Indirect Expenses:		
Staffing	565	419
Other indirect	102	23
	$ 667	$ 442
Total Research and Development	$ 6,417	$ 1,276

Off-balance Sheet Arrangements

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

Tabular Disclosure of Contractual Obligations

The following table sets forth our known contractual obligations for the periods indicated therein as of December 31, 2014.

	Payments due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1 – 3 years**	**3 – 5 years**	**More than 5 years**
Lease of office space	$ 1,456,000	$ 291,000	$ 940,000	$ 225,000	$ —
Total	$ 1,456,000	$ 291,000	$ 940,000	$ 225,000	$ —

We have minimum rental commitments of approximately $500 plus VAT for each month for our UK offices. The lease shall continue until it is terminated with three months prior written notice. Our contingent liability as of December 31, 2014 was approximately $1,500 to be paid during the first quarter of 2015. We also have total minimum rental commitments of approximately $1,454,000 for our US offices. The lease expires in August 2019. Minimum rental payments range from approximately $24,000 per month to approximately $29,000 per month.

The license agreement between Morria Biopharmaceuticals Inc. (the "Subsidiary") and Yissum, pursuant to which the Subsidiary was granted a global, exclusive license, including the right to grant sublicenses, subject to receipt of the prior consent of Yissum, which shall not be unreasonably withheld, includes the exclusive rights to produce, sell, market, import, distribute, and make any use of the technology, by both the Subsidiary and the sublicensees. If Yissum fails to respond within 15 days of receipt of the Company's written notice, then Yissum shall be deemed to have given consent to such sublicenses. The license agreement is valid for 20 years or until the last to expire patent. In exchange for granting the said license to the Subsidiary, Yissum will be entitled to the following royalties:

- 4% of the total sales that the Subsidiary or a related company thereof (as this term is defined in the license agreement); and
- 18% of the total payments or royalties that the Subsidiary will be entitled to receive from sublicensees.

On June 20, 2005, the Company executed with Yissum an agreement for providing research and development services, whereby Yissum grants the Company compound development services. It has been agreed that the intellectual property and the knowledge that will accumulate during the provision of the services will be owned by Yissum. Yissum has granted the Company a license to use the results of the service provision agreement, and the permission to grant a sublicense. The service agreement was renewed several times prior to 2011. On February 28, 2011, the service provision agreement was renewed again. In consideration for the performance of services the Company agreed to pay Yissum $70,000 plus overhead per year, depending on the work requested by the Company to be done at the sole and exclusive option of the Company during each year of the following five years.

Jumpstart Our Business Startups Act of 2012

The Jumpstart Our Business Startups Act of 2012, or JOBS Act, permits an emerging growth company such as us to take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. Among these provisions is an exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting. We have elected to rely on this exemption and will not provide such an attestation from our auditors.

We will remain an emerging growth company until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenue of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our ADSs that are held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required as we are a smaller reporting company.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Management's Report on Internal Control over Financial Reporting

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

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014, based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2014.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not apploicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

Our Articles of Association, as amended, provide that our business is to be managed by the board of directors (subject to any directions made by the members of the Company by special shareholder resolution). Our board of directors is divided into three classes for purposes of election (Class A Directors, who serve a one year term before being subject to re-election at the Company's annual general meeting; Class B Directors, who serve a two year term before being subject to re-election at the annual general meeting; and Class C Directors who serve a three year term before being subject to re-election at the annual general meeting, provided also that in any two year period, a majority of the board must stand for re-election). Our board of directors currently consists of seven members, classified into the three classes as set out in the table below. Mark Cohen serves as Executive Chairman of our board of directors. The following table presents the names of the current members of our board of directors.

Name	Director Class and Position
Mark S. Cohen	Class C Director — Executive Chairman of the Board;
Gur Roshwalb	Class A Director — Research & Development Committee
David Sidransky, M.D.	Class C Director — Compensation Committee (Chairman); Nominating and Corporate Governance Committee; Research & Development Committee
Dr. Johnson Yiu-Nam Lau, M.B.,B.S., M.D., F.R.C.P.	Class B Director — Nominating and Corporate Governance Committee (Chairman); Audit Committee
Amos Eiran	Class B Director — Audit Committee; Compensation Committee
Robert F. Doman	Class A Director — Research & Development Committee (Chairman; Compensation Committee; Nominating and Corporate Governance Committee.
Allan Shaw	Class A Director — Audit Committee (Chairman)

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

Mark S. Cohen, age 47, has served as the Chairman of our board of directors since December 21, 2004. Currently, he is a senior partner and the chair of the life sciences group at the law firm Pearl Cohen Zedek Latzer Baratz, LLP, which he joined in 1999. Mr. Cohen holds a B.A. in biochemistry from Rutgers University, an M.S. in biology from New York University and a J.D. from University of Baltimore School of Law. He is admitted to practice law in New York and New Jersey, and he is a registered patent attorney in the United States.

David Sidransky, M.D., age 54, has served as a member of our board of directors since June 13, 2007. Currently, Dr. Sidransky serves as a Prof. of Oncology at the Johns Hopkins University in Baltimore, and has held this position since 1996. He served as Vice Chairman of the Board of Directors of Imclone until the sale of the company to Eli Lily. He also serves as a member of the board of directors of Galmed (NASDAQ:GLMD), Advaxis (NASDAQ:ADXS), Orgenesis (OTC:ORGS), Rosetta Genomics (NASDAQ:ROSG) and Champions Oncology, Inc. (OTCBB: CSBR). Dr. Sidransky holds a B.S. in chemistry from Brandeis University and an M.D., specializing in Oncology, from Baylor College of Medicine.

Johnson Yiu Nam Lau, M.B.,B.S., M.D., F.R.C.P., age 54, has served as a member of our board of directors since May 2, 2007. Currently, he serves as the chairman and CEO of Kinex Pharmaceuticals LLC, a drug discovery and development biotech company, which he joined in 2003. He previously served as Chairman and CEO of Ribapharm, a publicly traded company listed in (NYSE: RNA), and as a member of the board of directors and Chairman of each of the Audit and Risk Management and Nominating and Corporate Governance Committees of Chelsea Therapeutics International, Ltd. (NASDAQ: CHTP). Dr. Lau holds an M.B.B.S. and M.D. from the University of Hong Kong and an M.R.C.P. and an F.R.C.P. from the Royal College of Physicians.

Amos Eiran, age 78, has served as a member of our board of directors since June 28, 2012. From November 1972 to June 1975 and from June 1977 to June 1988, he served as the CEO and Chairman of Mivtahim, Israel's largest pension fund. From June 1974 to May 1988, Mr. Eiran served as a director on the board of Bank HaPoalim and from August 1993 to August 1997, served as director on the board of Bank HaMizrahi, from March 1993 to August 1997, as chairman of BioLight Israeli Life Sciences Investments Ltd from March 2007 to May 2011. From May 1988 to August 1990, he served as the President of the University of Haifa. Since January 2000, he has been serving on the board of directors of Clal-Bituah and Delek Explorations. From June 1975 to June 1977, Mr. Eiran served as Director General of the Prime Minister's Office, during the term of Prime Minister Itzhak Rabin. Mr. Eiran holds a B.A. from American University (Washington DC) in humanities and M.A. in history from Tel Aviv University, and a diploma in institutional investments from Wharton School of Business.

Robert F. Doman, age 65, has served as a member of our board since June 20, 2013. Mr. Doman is a seasoned pharmaceutical and medical device executive with 30+ years of extensive international and domestic experience in general management, business development, building sales and marketing capabilities, new product development and strategic planning. Most recently Bob served as President and Chief Executive Officer of DUSA Pharmaceuticals, Inc., a publicly traded specialty pharmaceutical and medical device company focused in the field of dermatology. He joined DUSA in 2005 as President and Chief Operating Officer and was promoted to President and Chief Executive Officer in June 2007. DUSA was acquired by Sun Pharma in June of 2012. Prior to joining DUSA Pharmaceuticals, Bob served as President of Leach Technology Group, the medical electronic device, design, product development and contract manufacturing services division of privately held Leach Holding Corporation. From 1999 to 2000, Bob served as President, Device Product Development of West Pharmaceutical Services, a manufacturer of systems and device components for parentally administered medicines and drugs. From 1991 to 1999, Bob worked for the Convatec division of Bristol-Myers Squibb in positions that included: Vice President, Worldwide Marketing and Business Development; Vice President and General Manager, U.S. Wound and Skin Care; and Vice President, U.S. Operations. Earlier in his career, Bob held sales, marketing and business development roles of increasing responsibilities for Critikon, Inc., a Johnson and Johnson company. While serving as Business Director for Vascular Access he licensed and launched the first Intravenous Catheter with needle-stick protection, which is the industry standard today. He received a Bachelor's degree from Saint Joseph's University where he has served as a member of the Development Committee and the Haub School of Business Advisory Board.

Allan L. Shaw, age 50, has served as a member of our board of directors since October 2, 2013. Mr. Shaw currently leads Alvarez & Marsal's biopharmaceutical consulting practice and served as a member of the Board of Directors for the Central New York Biotech Accelerator (formerly Central New York-Biotech Research Center). Previously, he worked as Chief Financial Officer and executive management board member of Serono International S.A., a global biotechnology company and the largest in Europe. He was also the founder and Senior Managing Director of Shaw Strategic Capital LLC, an international financial advisory firm, focused on providing strategic financial counsel on a wide variety of issues such as general corporate finance, mergers and acquisitions, capital structuring, licensing and capital markets. His clients included a biopharmaceutical licensing/developmental group and an international investment bank, for which he served as a strategic adviser. Mr. Shaw has served as a Board member and Chief Financial Officer for NewLead Holdings LTD (NEWL), as well as an independent board member of Navios Maritime Holdings Inc.'s, serving as Chairman for Navios' Audit (designated financial expert) and Compensation Committees. He has contributed to several corporate governance books and is a member of the American Institute of Certified Public Accountants, New York Society of Certified Public Accountants and Corporate Directors Group. Mr. Shaw graduated with a Bachelor of Science from the State University of New York (Oswego College), and is a certified public accountant in the State of New York.

Executive Officers

There are no family relationships among officers and directors of Celsus.

The executive officers of Celsus are responsible for the day-to-day management of the Company. The following table lists the names and positions of our executive officers.

Name	Position
Gur Roshwalb, M.D.	Chief Executive Officer, Director
Dov Elefant	Chief Financial Officer
Pablo Jimenez, M.D.	Chief Medical Officer

Biographical information of our executive officers is set forth below.

Gur Roshwalb, age 46, has served as our Chief Executive Officer since March 4, 2013. Prior to joining us, from April 2008 to February 2012, Dr. Roshwalb was employed by Venrock, a leading venture capital firm, where he most recently served as a Vice President investing in both private and public healthcare companies. At Venrock, Dr. Roshwalb was involved in the valuation, diligence and deal structuring of numerous pharmaceutical and biotechnology companies. Prior to Venrock, Dr. Roshwalb was a senior equity analyst at Piper Jaffray from June 2004 to March 2008 where he published research on specialty pharmaceutical companies. Dr. Roshwalb was in private practice in New York and Board Certified in Internal Medicine before joining the investment community. He received an MBA from the NYU Stern School of Business, and an MD from the Albert Einstein College of Medicine.

Dov Elefant, age 47, has served as our Chief Financial Officer since January 11, 2012. From March 2011 until January 2012, he was Chief Financial Officer of Althera Medical Ltd. and from March 2009 to February 2011 he performed consulting services to a number of companies. He was also the Corporate Controller, from March 2007 to February 2009 for Lev Pharmaceuticals (OTCBB:LEVP), which was acquired by ViroPharma in 2008, Controller and Vice President of Finance and Administration at EpiCept Corporation (NASDAQ:EPCT.PK) from December 1999 to March 2007, Assistant Controller at Tetragenex Pharmaceuticals from November 1998 to October 1999 and held other accounting and finance roles from March 1991 to October 1998. Mr. Elefant holds a B.S. in accounting from Yeshiva University.

Pablo Jimenez, M.D., age 50, has served as our Chief Medical Officer since October 23, 2013. Dr. Jimenez is a senior pharmaceutical executive with more than twenty years of success in clinical development and medical affairs within the respiratory, dermatology, wound healing and oncology therapeutic areas. He brings a strong background in product business development in inflammation, immunology and tissue engineering. Within Novartis Pharma Clinical Development and Medical Affairs, he held positions of increasing responsibility including: Global Clinical Program Leader Apligraf®, Global Project Section Leader Elidel®, Global Brand Medical Director Xolair®, Global Head, Medical Services and Global Head of Medical Education & Communications. Dr. Jimenez worked at Novartis from May 2001 to September 2011. From September 2011 to March 2012, Dr. Jimenez was employed by Sotio, a Czech drug development company, as their Chief Medical Officer, where he was responsible for their global clinical portfolio, including clinical development, marketing strategy and regulatory compliance. From July 2012 to present, he has served as the founder and CEO of Qara Bio-Pharmaceutical Solution, LLC, a boutique medical writing and drug development strategy consulting firm. He received his MD from Central University School of Medicine in Ecuador and Master's Certificate in Project Management from the George Washington University School of Business and Public Management. Dr. Jimenez did his Post-Doctoral research work at Brown University, Division of Biology and Medicine.

Board Practices

Our Articles of Association, as amended, provide that our business is to be managed by the board of directors (subject to any directions made by the members of the Company by special shareholder resolution). Our board of directors is divided into three classes for purposes of election (Class A Directors, who serve a one year term before being subject to re-election at the Company's annual general meeting; Class B Directors, who serve a two year term before being subject to re-election at the annual general meeting; and Class C Directors who serve a three year term before being subject to re-election at the annual general meeting, provided also that in any two year period, a majority of the board must stand for re-election). Our board of directors currently consists of seven members, classified into the three classes as follows: (1) Gur Roshwalb, Robert F. Doman and Allan Shaw constitute Class A, with a term ending at the 2015 annual general meeting; (2) Amos Eiran and Dr. Johnson Lau constitute Class B, with a term ending at the 2015 annual general meeting; and (3) Mark Cohen and David Sidransky constitute Class C, with a term ending at the 2016 annual general meeting. Mark Cohen serves as Executive Chairman of our board of directors. The following table presents the names of the current members of our board of directors.

The following table sets forth the terms of our directors and when they are up for re-election:

Name	Commencement of Term	Expiration of Office
Mark S. Cohen	December 21, 2004	2016 annual general meeting
Dr. Gur Roshwalb, M.D.	June 19, 2014	2015 annual general meeting
Dr. David Sidransky, M.D.	June 13, 2007	2016 annual general meeting
Dr. Johnson Yiu Nam Lau, M.B.,B.S., M.D., F.R.C.P.	May 2, 2007	2015 annual general meeting
Amos Eiran	June 28, 2012	2015 annual general meeting
Robert F. Doman	June 20, 2013	2015 annual general meeting
Allan Shaw	October 2, 2013	2015 annual general meeting

Committees of the Board of Directors

The Committees of our Board of Directors consist of an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

Audit Committee

Our Audit Committee currently consists of three members, appointed by the board of directors: Allan Shaw, Dr. Johnson Yiu-Nam Lau and Amos Eiran, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the Audit Committee. Mr. Shaw is the chairman of our Audit Committee. Our board of directors has determined that Mr. Allan Shaw is the audit committee financial expert.

Compensation Committee

Our Compensation Committee currently consists of three members, appointed by the board of directors: Dr. David Sidransky, Robert F. Doman and Amos Eiran all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the Compensation Committee. Dr. Sidransky is the chairman of our Compensation Committee.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee currently consists of three members, appointed by our board of directors: Robert F. Doman, Dr. David Sidransky and Dr. Johnson Lau. Messrs. Sidransky, Doman and Lau are independent within the meaning of SEC corporate governance rules of independence for purposes of the Nominating and Corporate Governance Committee. Dr. Lau is the chairman of our Nominating and Corporate Governance Committee.

None of our directors have any service contracts with Celsus or any of our subsidiaries that provide for benefits upon termination of employment.

Scientific Advisors

We seek advice from our scientific advisory board, which consists of a number of leading scientists and physicians, on scientific and medical matters. Our scientific advisory board assesses:

- our research and development programs;
- new technologies relevant to our research and development programs; and
- specific scientific and technical issues relevant to our business.

The current members of our scientific advisory board are:

Name	Position/Institutional Affiliation
Jonathan K. Wilkin, MD, FAAD, FACP and the founding director (retired) of the Division of Dermatology and Dental Products at the US Food and Drug Administration	Jonathan K. Wilkin, MD, the founding director (retired) of the Division of Dermatology and Dental Products at the US Food and Drug Administration, remains active in regulatory matters after over 12 years of FDA service which included membership on the FDA's Dermatology Drugs Advisory Committee. Before going to the FDA, he was Director of Dermatology at the Ohio State University and Professor of Pharmacology and Medicine. He has over 130 publications in dermatology and clinical pharmacology. Dr. Wilkin received his BA and MS in zoology from Ohio State University in Columbus, followed by his medical degree from the Ohio State University College of Medicine. After a year of residency in obstetrics and gynecology at the University of Louisville, School of Medicine in Kentucky, he completed a residency in dermatology at the University of Tennessee Health Science in Memphis, where he was Chief Resident. Dr. Wilkin has served as chairman of the medical advisory board for the National Rosacea Society from 1998 to 2012 as well as having chaired their Expert Committees on the Classification and Staging System for Rosacea. He also serves on the American Academy of Dermatology's (AAD) Ad Hoc Task Force on the Academy's Efforts with FDA and on their Environment and Drugs Committee. Dr. Wilkin has been active in the American Society for Clinical Pharmacology and Therapeutics, having chaired the Dermatologic and Allergic Diseases Section and the Constitution and By-laws Committee for several years, as well as serving in other capacities.

	Dr. Wilkin is a fellow of both the AAD and the American College of Physicians, a member of the American Dermatological Association and board certified by both the American Board of Dermatology and the American Board of Clinical Pharmacology.
Professor Amy Paller, MD, MS. Walter J. Hamlin Chair and Professor of Dermatology, Professor of Pediatrics, and Principal Investigator of the NIH-funded Skin Disease Research Center at Northwestern University's Feinberg School of Medicine	Amy Paller, MD, MS is the Walter J. Hamlin Chair and Professor of Dermatology, Professor of Pediatrics, and Principal Investigator of the NIH-funded Skin Disease Research Center at Northwestern University's Feinberg School of Medicine. She received her undergraduate and graduate degrees from Brown University and her medical degree from Stanford University. Dr. Paller completed residency training in Pediatrics and Dermatology at Northwestern University and her postdoctoral research fellowship at University of North Carolina. She served on the Board of Directors of the American Academy of Dermatology and the American Dermatological Association, and as President of the Society for Pediatric Dermatology, Society for Investigative Dermatology, and the Women's Dermatologic Society. An author of more than 350 original publications, Dr. Paller is an NIH-funded investigator who conducts both laboratory-based and often landmark clinical investigations, particularly related to inflammatory skin disease and genetic skin disorders.
Dr. Carle Paul, Professor and Chairman of the Department of Dermatology at Paul Sabatier University, Toulouse, France	Dr. Carle Paul is Professor and Chairman of the Department of Dermatology at Paul Sabatier University, Toulouse, France. The department is the Dermatology reference center for the 3 million people of the Midi-Pyrenees region and includes inpatient, day-care center and outpatient clinics, a clinical research center (phase I to IV) and teaching facilities. The department comprises 10 full time physicians, 6 residents and 8 part time dermatologists. He completed his dermatology training in 1988 – 1994 in Paris, including a one-year research scholarship in the immunology laboratory of JF Bach at Paris Descartes University and INSERM U25 working on apoptosis induction and mechanism of toxic epidermal necrolysis. Professor Paul holds a master in Fundamental Immunology and a PhD in Pharmacology. He was Board member of the European Academy of Dermatology and Venereology (2007 – 2012) and is currently Secretary General of the EADV (2012 – 2016). He was appointed Junior Lecturer in Dermatology and Director of the Clinical Pharmacology Unit in 1994 – 1997 at Saint Louis Hospital and Paris VII University. In 1998 – 2005, he worked in pharmaceutical research in Basel, Switzerland, while maintaining part-time clinical appointment at the Department of Dermatology, Mulhouse, France. Professor Paul is co-inventor of 8 patents and author of over 200 peer reviewed publications. His areas of research interest are inflammatory skin diseases, mainly atopic dermatitis and psoriasis, pharmacology and clinical drug development.

Dr. Lawrence F. Eichenfield, Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, and Professor of Pediatrics and Medicine (Dermatology), at the University of California, San Diego (UCSD) School of Medicine	Dr. Lawrence F. Eichenfield is Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, and Professor of Pediatrics and Medicine (Dermatology), at the University of California, San Diego (UCSD) School of Medicine. He earned his medical degree from Mount Sinai School of Medicine in New York, was a pediatric resident and chief resident at Children's Hospital of Philadelphia, and completed dermatology training at the Hospital of the University of Pennsylvania. He has been board certified in pediatrics, dermatology and pediatric dermatology. He is Editor-in-Chief of Pediatric Dermatology and serves on the editorial boards of multiple journals and periodicals. Dr. Eichenfield has published more than 250 journal articles, chapters and abstracts, and books, and is senior editor of Neonatal & Infant Dermatology, published by Elsevier, and The Eczemas published by Summit Communications. He is Director of Rady Children's Hospital Eczema & Inflammatory Disease Center and the Vascular Lesion & Birthmark Center. He is past president of the Society for Pediatric Dermatology, has served on the Board of the American Academy of Dermatology, and served as Chair for the 69 th Annual Meeting of the American Academy of Dermatology. Dr. Eichenfield is a founding board member and President of the American Acne & Rosacea Society, and is Co-Chair of the Pediatric Dermatology Research Alliance (PeDRA), a collaborative research network.
Emma Guttman-Yassky, MD, PhD Associate Professor of Dermatology & Immunology, Director, Center For Excellence in Eczema Director, Contact Dermatitis Clinic Director of the Laboratory of Inflammatory Skin Diseases Mount Sinai Hospital, New York	Dr. Emma Guttman-Yassky is an Associate Professor of Dermatology & Immunology and Director of the Center for Excellence in Eczema and the Occupational/Contact Dermatitis Clinic and the Director of the Laboratory of Inflammatory Skin Diseases in the Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York, and an adjunct associate professor at the Rockefeller University. She earned her MD degree from the Sackler School of Medicine at the Tel-Aviv University, and a PhD degree from the Bar-Ilan University, Ramat-Gan, Israel. Dr. Guttman completed her first dermatology residency at the Dermatology Department at the Rambam Medical Center/Technion Institute in Haifa. After obtaining her Israeli Board certification in dermatology, Dr. Guttman moved to the U.S. to pursue a two-year postdoctoral fellowship as a clinical scholar at The Rockefeller University in the Laboratory for Investigative Dermatology. Upon completion of her fellowship, she became board-certified by the American Board of dermatology after obtaining her second dermatology residency training at the Weill-Cornell Medical College, in New York. Dr. Guttman's major clinical focus is atopic dermatitis/eczema and contact/occupational dermatitis. She has performed groundbreaking research and published extensively on eczema and inflammatory skin diseases. Emma Guttman is now the pre-eminent dermatologist studying molecular and cellular pathomechanisms of eczema in humans, and made paradigm-shifting observations on the immunologic mechanisms involved, with important therapeutic implications, opening the door to new therapeutic discoveries. She has been the first to identify the importance of the IL-22 cytokine in eczema and has recently received an NIH grant to study the therapeutic effects of blocking Th22 cell/IL-22 in patients with eczema. Her research made paradigm-shifting discoveries on the immunologic basis of eczema in humans, enriching the understanding of the pathophysiology of this common disorder and opening the door to new therapeutic discoveries. She is now testing novel therapeutics developed for eczema in clinical trials aimed to ultimately improve the quality of lives of patients with eczema. She is the recipient of the prestigious Young Investigator Award (2011) from the American Academy of Dermatology, the 2011 recipient of the Dermatology Foundation's Physician-Scientist Career Development Award, and the Everett C. Fox Award for best clinical research at the Residents & Fellows Symposium of the American academy of dermatology in 2004. Recently, Dr. Guttman has been awarded several important federal and foundation grants. She received a large NIH/NIAMS grant to perform a proof of concept study on the role of Th22 T-cells in atopic dermatitis/eczema using a novel anti IL-22 antibody. She has also secured a grant from the LEO Foundation to study immune and terminal differentiation biomarkers in pediatric AD, as well as an award from the National Institute of Allergy and Infectious Diseases (NIAID) to participate in a multi-center study on the role of infections in AD. She has also received support from pharmaceutical companies, allowing analyses of biopsies of patients with eczema treated with novel therapeutics, underscoring her recognition as an outstanding physician-scientist in the dermatology community.

Dr. Guttman has made paradigm-shifting discoveries on the immunologic basis of atopic dermatitis/eczema (AD) in humans, enriching the understanding of the pathophysiology of this common disorder and opening the door to new therapeutic discoveries. She is now testing novel therapeutics developed for eczema in clinical trials aimed to ultimately improve the quality of lives of patients with eczema.

She is the recipient of the prestigious Young Investigator Award (2011) from the American Academy of Dermatology, the 2011 recipient of the Dermatology Foundation's Physician-Scientist Career Development Award, and the Everett C. Fox Award for best clinical research at the Residents & Fellows Symposium of the American academy of dermatology.

Recently, Dr. Guttman has been awarded several important federal and foundation grants. She received a large NIH grant to do a proof of concept study on the role of Th22 T-cells in atopic dermatitis/eczema using a novel anti IL-22 antibody.

She has also secured a grant from the LEO Foundation to study immune and terminal differentiation biomarkers in pediatric AD, as well as an award from the National Institute of Allergy and Infectious Diseases (NIAID) to participate in a multi-center study on the role of infections in AD.

Additionally, she received support from pharmaceutical companies, underscoring her recognition as an outstanding physician-scientist in the dermatology community. She is doing many mechanistic studies involving clinical trials with new therapeutics in patients atopic dermatitis around the globe.

Her research on eczema has contributed directly to the recently developed treatments for this disease, earning her a unique place in dermatology and immunology worldwide. She is now invited to speak not only nationally, but also in Europe and Japan on novel developments in eczema and its therapeutics.

Marc E. Rothenberg MD, PhD Director, Division of Allergy and Immunology Director, Cincinnati Center for Eosinophilic Disorders Professor of Pediatrics Cincinnati Children's Hospital Medical Center University of Cincinnati College of Medicine	Dr. Rothenberg is director of the Division of Allergy/Immunology at Cincinnati Children's Hospital Medical Center and tenured professor of pediatrics at Cincinnati Children's and University of Cincinnati College of Medicine. He has helped build a top program in research, and his division is a leader in allergy and immunology. His research is focused on molecular analysis of allergic inflammation, primarily on the molecular pathogenesis of eosinophilic esophagitis. His awards include the 2007 E Mead Johnson Award from the Society of Pediatric Research, 2010 National Institutes of Health MERIT Award, and being elected an American Association for the Advancement of Science fellow. His publications number more than 300. He graduated summa cum laude with highest honors in chemistry and biochemistry from Brandeis University and completed the MD/PhD program at Harvard Medical School.

Limitations on Liability and Indemnification Matters

To the extent permitted by the Companies Act 2006, we shall indemnify our directors against any liability. We maintain directors and officers insurance to insure such persons against certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us under the foregoing provisions, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and therefore is unenforceable.

Section 16(a) Beneficial Ownership Reporting Compliance

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis. An Annual Statement of Beneficial Ownership on Form 5 is not required to be filed if there are no previously unreported transactions or holdings to report.

Code of Ethics

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

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows the compensation paid or accrued during the last two fiscal years ended December 31, 2013 and 2014 to (1) our Chief Executive Officer, (2) our Chief Financial Officer, and (3) our Chief Medical Officer, our named executive officers ("NEOs").

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) [1]	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Gur Roshwalb, M.D., Chief Executive Officer [2]	2014	350,000	-	—	60,564	—	—	—	410,564
	2013	287,493	115,500	—	173,396	—	—	—	576,389
Dov Elefant, Chief Financial Officer	2014	200.000	-	—	20,188	—	—	—	220,188
	2013	163,472	50,000	—	25,120	—	—	—	238,592
Pablo Jimenez, M.D., Chief Medical Officer [3]	2014	240,000	—	—	-	—	—	—	240,000
	2013	40,000	—	—	50,771	—	—	—	90,771

(1) These amounts represent the aggregate grant date fair value for option awards for fiscal years 2013 and 2014, respectively, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in our Financial Statements, included in our Annual Report on Form 20-F for the year ended December 31, 2013 and this Annual Report on Form 10-K for the year ended December 31, 2014.
(2) Dr. Roshwalb has served as our Chief Executive Officer since March 4, 2013.
(3) Dr. Jimenez has served as our Chief Medical Officer since October 23, 2013.

Employment and Consulting Agreements

Dr. Gur Roshwalb. On March 4, 2013, we entered into an employment agreement with Dr. Roshwalb to be our Chief Executive Officer. The employment agreement, which is governed by New York law, is terminable by either party, upon three months' prior written notice. In addition, we are entitled to terminate Dr. Roshwalb's employment immediately, under certain circumstances, including, among other things, upon the occurrence of a material, recurring, continuing or fundamental breach of his obligations under the employment agreement, bankruptcy, inability to perform his duties under the employment agreement or criminal conviction under certain circumstances.

The annualized salary of Dr. Roshwalb shall be $350,000, plus reimbursement of out-of-pocket expenses incurred by him in the course of his duties. The board of directors will review Dr. Roshwalb's salary annually, although it is not obligated to increase it. In addition, he is entitled to receive an option to purchase 560,000 Ordinary Shares under our stock option plan as soon as practicable following our June 2013 Annual General Meeting. The exercise price of such option will be equal to the greater of $2.00 per Ordinary Share or the fair market value (as such term in defined by the option plan) of an Ordinary Share on the effective date of the grant. On each anniversary of the effective grant date, 25% of the shares subject to the option shall vest, subject to Dr. Roshwalb's continued employment on each such vesting date and full vesting upon a change of control. Upon our closing of a financing of issued securities of no less than $15,000,000, Dr. Roshwalb shall be granted an option to purchase 100,000 Ordinary Shares under our option plan, which shall have the same exercise price and same vesting provisions as set forth above. At the sole discretion of the Board of Directors or the Compensation Committee of the Board, following each calendar year of employment, Dr. Roshwalb shall be eligible to receive an additional cash bonus of up to thirty-three percent (33%) of his base salary, based on the attainment of certain clinical development, and/or business milestones to be established annually by the Board or the Compensation Committee. On September 24, 2013, Dr. Roshwalb was granted options to purchase up to 660,000 Ordinary Shares under the ESOP at an exercise price of $2.00, which options fully vest on September 24, 2017.

Upon termination of Dr. Roshwalb's employment without cause, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 12 months of base salary at the highest annualized rate in effect at any time before the employment terminates payable in substantially equal installments. Dr. Roshwalb shall also be entitled to COBRA continuation coverage paid in full by us for up to a maximum of twelve (12) months following the date of termination.

The employment agreement includes a non-competition covenant that, during the term of his employment by us, Dr. Roshwalb cannot be involved, directly or indirectly, in any competing activity or any activity that may pose competition to or harm us, and for a period of six months after the termination of the agreement with us, to be involved in or provide any consultation services to any business that competes, or that is likely to compete with our business. Dr. Roshwalb also cannot engage in any activity outside the scope of his employment without our prior approval. Dr. Roshwalb is also obligated to keep confidential the confidential information of our company. In addition, the intellectual property and the technology that are developed during the provision of these services will be owned by us.

Dov Elefant. Effective January 11, 2012, we entered into an employment agreement with Mr. Elefant, our Chief Financial Officer. The employment agreement, which is governed by English law, is terminable by either party, upon three months' prior notice. In addition, we are entitled to terminate Mr. Elefant's employment immediately, under certain circumstances, including, among other things, upon the occurrence of a material, recurring, continuing or fundamental breach of his obligations under the employment agreement, bankruptcy, inability to perform his duties under the employment agreement or criminal conviction under certain circumstances. The board of directors will review Mr. Elefant's salary annually, although it is not obligated to increase it.

The annualized salary of Mr. Elefant was $150,000, plus reimbursement of out-of-pocket expenses incurred by him in the course of his duties. Effective with the closing of the September private placement, Mr. Elefant annualized salary increased to $200,000. Under the terms of his employment agreement, on June 20, 2012, the Board granted Mr. Elefant options to purchase up to 40,000 Ordinary Shares under the ESOP at an exercise price of $1.56 per share, which options fully vested on January 11, 2013. On September 24, 2013, Mr. Elefant was granted options to purchase up to 100,000 Ordinary Shares under the ESOP at an exercise price of $2.00, which options fully vest on July 1, 2014.

The employment agreement includes a non-competition covenant that, during the term of his employment by us, Mr. Elefant cannot be involved, directly or indirectly, in any competing activity or any activity that may pose competition to or harm us, and for a period of six months after the termination of the agreement with us, to be involved in or provide any consultation services to any business that competes, or that is likely to compete with our business. Mr. Elefant also cannot engage in any activity outside the scope of his employment without our prior approval. Mr. Elefant is also obligated to keep confidential the confidential information of our Company. In addition, the intellectual property and the technology that are developed during the provision of these services will be owned by us.

Pablo Jimenez, M.D. On October 23, 2013, we entered into an employment agreement with Dr. Pablo Jimenez to be our Chief Medical Officer. The employment agreement, which is governed by New York law, is terminable by either party upon three months' prior notice. In addition, we are entitled to terminate Dr. Jimenez's employment immediately, under certain circumstances, including, among other things, upon the occurrence of a material, recurring, continuing or fundamental breach of his obligations under the employment agreement, bankruptcy, inability to perform his duties under the employment agreement and criminal conviction under certain circumstances.

The annualized salary of Dr. Jimenez shall be $240,000 (or $20,000 per month), plus reimbursement of out-of-pocket expenses incurred by him in the course of his duties. In addition, he is entitled to receive options to purchase 200,000 Ordinary Shares under our ESOP plan, of which 70,000 shares of the Ordinary Shares are subject to attainment of certain clinical development, and/or business milestones over the course of the next sixteen (16) months as follows: execution and completion of first interpretable results in atopic dermatitis trial, and IND filing/acceptance. At the sole discretion of the Board of Directors, following each calendar year of employment, Mr. Jimenez shall be eligible to receive an additional cash bonus of up to twenty-five percent (25%) of his base salary, based on the attainment of certain clinical development, and/or business milestones over the course of the next sixteen (16) months.

The employment agreement includes a non-competition covenant that, during the term of his employment by us, Dr. Jimenez cannot be involved, directly or indirectly, in any competitive activity or any other activity that may pose competition to or harm us, and for a period of six months after the termination of employment with us, to be involved in or provide any consultation services to any business that competes, or that is likely to compete with our business. Also, Dr. Jimenez may not engage in any activity outside the scope of his employment without our prior approval. Dr. Jimenez is also obligated to keep confidential the confidential information of our Company. Moreover, the intellectual property and the technology that are developed during the provision of these services will be owned by us.

Outstanding Equity Awards at Fiscal Year-End

	Option Awards				
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)**	**Option Exercise Price ($)**	**Option Expiration Date**
Gur Roshwalb, M.D.	140,000	420,000(1)	—	2.00	9/24/2023
	25,000	75,000(2)	—	2.00	9/24/2023
	120.000(3)	-		0.75	2/5/2024
Dov Elefant	40,000	—	—	1.56	1/11/2022
	100,000	-(2)	—	2.00	7/1/2023
	40,000(3)	-		0.75	2/5/2024
Pablo Jimenez, M.D.	32,500	97,500(4)	—	0.57	11/1/2023
	—	—	70,000(5)	0.57	11/1/2023

(1) These options were granted on September 23, 2013, and are exercisable over a four-year period with one-fourth of the options granted vesting on September 23 each year through 2017.
(2) These options were granted on September 23, 2013, and are fully exercisable on July 1, 2014.
(3) These options were granted on February 2, 2014, and are fully exercisable on May 31, 2014.
(4) These options were granted on November 1, 2013, and are exercisable over a four-year period with one-fourth of the options granted vesting on November 1 each year through 2017.
(5) These options were granted on November 1, 2013, and will vest upon attainment of certain clinical development milestones.

Director Compensation

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

Based on the recommendation of our compensation committee, our board of directors adopted a non-employee director compensation policy on February 11, 2015. Under the 2015 policy, our non-employee directors will be compensated for service on our board of directors as follows in 2015:

- an annual retainer for our non-employee directors for service on our board of directors of $35,000;
- for the chairman of the board and each of the chairpersons of the audit committee, compensation committee, nominating and governance committee and the research and development committee, an annual fee of $15,000;
- to each newly elected director, an initial grant of a stock option to purchase 25,000 ordinary shares, at an exercise price equal to the fair market value of our ordinary shares on the date of grant, which option shall vest in one year on the anniversary of the date of grant;
- for continuing service on our board of directors, an annual grant of a stock option to purchase 25,000 ordinary shares, at an exercise price equal to the fair market value of our ordinary shares on the date of grant, which option shall vest in one year on the anniversary of the date of grant;
- for each of the chairpersons of the audit committee, compensation committee, nominating and governance committee and the research and development committee, an annual grant of a stock option to purchase 20,000 ordinary shares, at an exercise price equal to the fair market value of our ordinary shares on the date of grant, which option shall vest in one year on the anniversary of the date of grant; and
- for the chairman of the board, an annual grant of a stock option to purchase 20,000 ordinary shares, at an exercise price equal to the fair market value of our ordinary shares on the date of grant, which option shall vest in one year on the anniversary of the date of grant.

Each of these options shall be granted under our 2014 Equity Incentive Plan, terminate 10 years after the grant date and become fully vested immediately prior to a change of control. The policy also provides that directors may elect, in lieu of annual cash payments, to receive, in part or in full, fully-vested ordinary shares equal to the dollar-value of the non-cash portion of their annual compensation, calculated in accordance with FASB Accounting Standards Codification ASC 718, “Share-Based Payment” on the payment date.

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

During 2014, our policy was the same as our 2015 policy except that the annual retainer for non-employee directors was $25,000 and the annual fee for the chairman of the board and each of the chairpersons of the audit committee, compensation committee, nominating and governance committee and the research and development committee was $10,000. The following table sets forth information regarding the total compensation awarded to, earned by or paid to each of our non-employee directors during the year ended December 31, 2014 for their service on our board of directors. Dr. Roshwalb, our chief executive officer, did not receive any additional compensation for his service as a director during 2014. The compensation that we pay to Dr. Roshwalb is discussed under "Executive Compensation" above.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Mark S. Cohen	35,000	59,211(2)	94,211(6)
Robert Doman	35,000	30,898(3)	65,898
Amos Eiran	25,000	22,774(4)	47,774
Johnson Yiu Nam Lau, M.B., B.S., M.D., F.R.C.P.	25,000	30,898(3)	55,898
Allan Shaw	35,000	40,992(5)	75,992
David Sidransky, M.D.	35,000	40,992(5)	75,992

(1) These amounts represent the aggregate grant date fair value of options granted to each director during the year ended December 31, 2014 computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in our Financial Statements, included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

(2) Fair value of the options granted on February 5, 2014 was $0.50 per share and fair value of the options granted on July 22, 2014 was $0.41. 130,000 options remain outstanding as of December 31, 2014.

(3) Fair value of the options granted on February 5, 2014 was $0.50 per share and fair value of the options granted on July 22, 2014 was $0.41.. 70,000 options remain outstanding as of December 31, 2014.

(4) Fair value of the options granted on February 5, 2014 was $0.50 per share and fair value of the options granted on July 22, 2014 was $0.41. 50,000 options remain outstanding as of December 31, 2014.

(5) Fair value of the options granted on February 5, 2014 was $0.50 per share and fair value of the options granted on July 22, 2014 was $0.41. 90,000 options remain outstanding as of December 31, 2014.

(6) Does not include payments of an aggregate of $960,409 for intellectual property legal services in 2014 made to Pearl Cohen Zedek Latzer Baratz LLP, of which Mr. Cohen is a senior partner.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of our outstanding Ordinary Shares as of February 11, 2015:

- each of our directors and executive officers individually;
- all of our directors and executive officers as a group; and
- each person known to us to own beneficially 5% or more of our Ordinary Shares.

Beneficial ownership generally includes voting or investment power over securities. Percentage of beneficial ownership is based on 55,636,283 of our Ordinary Shares outstanding as of February 11, 2015.

Our principal shareholders do not have different or special voting rights.

Unless otherwise noted, the principal address of each of the directors and officers listed below is Celsus Therapeutics Plc, 53 Davies Street, London, United KingdomW1K 5JH.

	Number of Ordinary Shares Beneficially Owned [1]	Percentage of Ordinary Shares Beneficially
Directors and Executive Officers		
Mark S. Cohen	2,144,540[2]	3.8%
Dr. Johnson Yiu Nam Lau, M.B.,B.S., M.D., F.R.C.P.	171,583[3]	*
David Sidransky, M.D.	329,042[4]	*
Amos Eiran	63,333[5]	*
Dov Elefant	180,000[6]	*
Gur Roshwalb, M.D.	460,438[7]	*
Pablo Jimenez, M.D.	32,500[8]	*
Robert F. Doman	48,333[9]	*
Allan Shaw	111,863[10]	*
All directors and officers as a group (9 persons)	3,541,632	6.3%
5% or More Shareholders		
Baker Bros. Advisors LP and affiliates	6,929,822[11]	12.5%
Franklin Advisors, Inc.	7,017,544[12]	12.6%
Broadfin Capital	4,708,772[13]	8.5%
Sabby Management, LLC	5,385,000[14]	9.7%
Prof. Saul Yedgar, Ph.D.	3,793,375[15]	6.1%

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

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Beneficial ownership also includes Ordinary Shares subject to options and other convertible securities that are exercisable or convertible within 60 days of February 11, 2015. Except as indicated by footnote, to our knowledge, all persons named in the table above have sole voting and investment power with respect to all Ordinary Shares shown as beneficially owned. Beneficial ownership of 5% or more shareholders is based solely on information disclosed in Schedule 13Gs and Form 4s filed with the SEC.

(2) Includes options to purchase, 136,500 Ordinary Shares at an exercise price of £0.80 per share (or $1.30) which expire on August 28, 2017 and 60,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on June 20, 2022, 75,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on March 19, 2022, 65,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024, 33,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and warrants to purchase 182,450 Ordinary Shares at an exercise price of $2.00 per share. This figure does not take into account a warrant issued to Pearl Cohen Zedek Latzer Baratz Law Office, or PCZL, on February 12, 2012, to purchase 309,492 ordinary Shares at an exercise price of $2.00 per share; Mark Cohen is a senior partner in PCZL. His business address is Pearl Cohen Zedek Latzer Baratz, LLP, 1500 Broadway, 12 th Floor, New York, NY 10036, United States of America.

(3) Consists of options to purchase 68,250 Ordinary Shares at an exercise price of £0.80 per share (or $1.30), which expire on August 28, 2017, 30,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on June 20, 2022, 25,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on March 19, 2022, 23,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and 25,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024. Dr. Johnson's business address is c/o Kinex Pharmaceuticals, 701 Ellicott Street, Buffalo, New York 14203.

(4) Includes options to purchase 128,477 Ordinary Shares at an exercise price of £0.80 per share (or between $1.29 and $1.30), 68,250 Ordinary Shares which expire on August 28, 2017, and 60,227 Ordinary Shares which expire on February 5, 2018. In addition, includes options to purchase 30,000 Ordinary Shares at an exercise price of $1.56 per share which expire on June 20, 2022, 25,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on March 19, 2022, 33,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and 45,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024 and warrants to purchase 12,500 Ordinary Shares at an exercise price of $2.00 per share which expire February 12, 2017. Dr. Sidransky's business address is 17 Pinsker Street, Rehovot, Israel 7630825.

(5) Includes options to purchase 15,000 Ordinary Shares at an exercise price of $2.00 which expire on June 28, 2022, 23,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and 25,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024. Mr. Eiran's business address is 2 Avner Street, Herzlia, Israel 4670402.

(6) Includes options to purchase 40,000 Ordinary Shares at an exercise price of $1.56 which expire on January 11, 2022, 100,000 Ordinary Shares at an exercise price of $2.00 per share, which expire on July 1, 2023 and 40,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024.

(7) Includes options to purchase 165,000 Ordinary Shares at an exercise price of $2.00 per share, which expire on September 24, 2023 and 120,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024.

(8) Includes options to purchase 32,500 Ordinary Shares at an exercise price of $0.57 per share, which expire on November 1, 2023.

(9) Includes options to purchase 23,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and 25,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024.

(10) Includes options to purchase 33,333 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023 and 45,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024.

(11) The number of shares beneficially owned includes 4,557,332 Ordinary Shares directly owned by Baker Brothers Life Sciences, L.P. ("Life Sciences"), a limited partnership, the sole general partner of which is Baker Brothers Life Sciences Capital, L.P., a limited partnership, the sole general partner of which is Baker Brothers Life Sciences Capital (GP), LLC, 591,452 Ordinary Shares directly owned by 667, L.P. (accounts #1 and #2) ("667"), a limited partnership, the sole general partner of which is Baker Biotech Capital, L.P., a limited partnership, the sole general partner of which is Baker Biotech Capital (GP), LLC, and 114,378 Ordinary Shares directly owned by 14159, L.P. ("14159" and together with Life Sciences, 667 and 14159, the "Baker Entities"), a limited partnership, the sole general partner of which is 14159 Capital, L.P., a limited partnership, the sole general partner of which is 14159 Capital (GP). Julian C. Baker and Felix J. Baker are the controlling members of the general partners of the general partners of the Baker Entities. Baker Bros. Advisors LP and affiliates (the "Adviser") serves as the Investment Adviser to each of the Baker Entities. Pursuant to amended and restated management agreements between the Adviser, each of the Baker Entities and the general partners of the Baker Entities, the Adviser has complete and unlimited discretion and authority with respect to the Baker Entities investments and voting power over investments. Julian C. Baker and Felix J. Baker are the principals of the Adviser and each may be deemed to control the Adviser and to indirectly beneficially own the shares beneficially owned by it. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the securities directly owned by the Baker Entities, and this disclosure shall not be deemed to be an admission that Julian C. Baker and/or Felix J. Baker are the beneficial owners of such securities for purposes of Section 13(d) or any other purpose. The address for Baker Bros. Advisors LP and its affiliates is 667 Madison Avenue, 21 st Floor, New York, NY 10065.

(12) Franklin Advisors, Inc. ("FAV"), an indirectly wholly owned subsidiary of a public traded company, Franklin Resources, Inc. ("FRI"), is the beneficial owner of these securities for purposes of Rule 13d-3 under the Exchange Act in its capacity as the investment adviser to Franklin Strategic Series — Franklin Biotechnology Discovery Fund and Franklin Templeton Investment Funds — Franklin Biotechnology Discovery Fund. When an investment management contract (including a sub-advisory agreement) delegates to FAV investment discretion or voting power over the securities held in the investment advisory accounts that are subject to that agreement, FRI treats FAV as having sole investment discretion or voting authority, as the case may be, unless the agreement specifies otherwise. Accordingly, FAV reports for purposes of Section 13(d) of the Exchange Act that it has sole investment discretion and voting authority over the securities covered by any such investment management agreement, unless otherwise specifically noted. The address for FAV is One Franklin Parkway, Building 920, San Mateo, CA 94403.

(13) Broadfin Capital, LLC serves as investment adviser to Broadfin Healthcare Master Fund, LTD with the power to direct investments and/or sole power to vote the shares owned by Broadfin Healthcare Master Fund, LTD. Kevin Kotler, a natural person, is the Managing Member of Broadfin Capital, LLC. Mr. Kotler has voting and dispositive power over the shares held by Broadfin Healthcare Master Fund, LTD. Mr. Kotler disclaims beneficial ownership of all shares beneficially owned, except to the extent of his pecuniary interests in such shares. The address for Broadfin Capital, LLC is 237 Park Avenue, Suite 900, New York, NY 10017.

(14) Sabby Healthcare Volatility Master Fund, Ltd. has indicated that Hal Mintz has voting and investment power over the shares held by it. The Sabby Healthcare Volatility Master Fund, Ltd. has also indicated that Sabby Management, LLC serves as its investment manager, that Hal Mintz is the manager of Sabby Management, LLC and that each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over these shares except to the extent of any pecuniary interest therein. The address for Sabby Management, LLC is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey, 07458.

(15) Includes the purchase of shares as described in footnote (2) above and the deduction of 101,400 Ordinary Shares purchased by the Yedgar Family Trust on January 24, 2012 by exercising a warrant granted by Prof. Yedgar. Prof. Yedgar's business address is c/o Department of Biochemistry, Hebrew University-Hadassah Medical School, Jerusalem, Israel 91120.

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

Certain Relationships and Related Party Transactions

Pursuant to our audit committee charter, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us have or will have a direct or indirect material interest.

The following discloses, since January 1, 2011, certain related party transactions involving us.

The law firm of Pearl Cohen Zedek Latzer Baratz LLP, or PCZL, represents us in intellectual property and commercial matters. Mark Cohen, the Chairman of our board of directors, is a senior partner in PCZL. PCZL charges us for services it renders on an hourly basis and expenses incurred. For the years ended December 31, 2014 and 2013 and 2012, we received invoices from PCZL for services rendered and expenses incurred for approximately $749,000, $555,000 and $365,000, respectively, and made payments to PCZL of approximately $960,409, $944,070 and $148,307, respectively. In 2012, we agreed with PCZL to satisfy $309,000 of the then outstanding balance owed to PCZL by our issuance on February 12, 2012, of a warrant to purchase up to 309,492 our Ordinary Shares at an exercise price of $2.00 per share, such warrant to expire on February 12, 2017, or the PCZL Warrant. We intend to continue using the legal services of PCZL in the future.

On January 18, 2005, Prof. Yedgar granted Mark Cohen a call option to purchase up to 50,700 Ordinary Shares at a purchase price of $0.016 per share and (ii) on March 12, 2007, Prof. Yedgar granted Mark Cohen a call option to purchase up to 152,000 Ordinary Shares at £0.01 per share, as amended on March 1, 2011. On January 8, 2015, Mr. Cohen exercised these options.

In March 2012, the members of the board of directors unconditionally waived any director's cash compensation for their service from March 2012 until the Company will raise an aggregate financing of at least $15,000,000 in private placement issuances.

From January 2012 through September 2013, we sold an aggregate of 280,025 Ordinary Shares to Mark Cohen, our Executive Chairman, at a price of $2.00 per share, for total gross proceeds of $560,050. In connection with such purchases, Mr. Cohen also received warrants to purchase an aggregate of 182,450 Ordinary Shares, at an exercise price of $2.00 per share.

On April 30, 2013, we sold an aggregate of 25,000 Ordinary Shares to Gur Roshwalb, our Chief Executive Officer, at a price of $2.00 per share, for total gross proceeds of $50,000. In connection with such purchase, Dr. Roshwalb also received warrants to purchase an aggregate of 12,500 Ordinary Shares, at an exercise price of $2.00 per share. In addition, on September 24, 2013, we sold an aggregate of 87,719 ordinary shares for a purchase price of $50,000 and also on September 24, 2013, in connection with the most favored nation terms, Dr. Roshwalb exchanged his warrants for an additional 62,719 Ordinary Shares.

Director Independence

Under Rules 5605 and 5615 of the NASDAQ Marketplace Rules, a majority of a listed company's board of directors must be comprised of independent directors within one year of listing. In addition, NASDAQ Marketplace Rules require that, subject to specified exceptions, including certain phase-in rules, each member of a listed company's audit, compensation and nominating and governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2) of the NASDAQ Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our Board of Directors has determined that Messrs. Shaw, Eiran, Doman, Dr. Lau and Dr. Sidransky are independent under the applicable rules and regulations of the NASDAQ Stock Market. Our Board of Directors also determined that Dr. David Sidransky, Messrs. Doman and Eiran, who comprise our Compensation Committee; and Mr. Doman, Dr. Sidransky and Dr. Lau, who comprise our Nominating and Governance Committee, all satisfy the independence standards for such committees established by the SEC and the NASDAQ Marketplace Rules, as applicable. Our Audit Committee currently consists of three members, appointed by the board of directors: Messrs. Shaw and Eiran and Dr. Lau, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the Audit Committee. In making such determinations, our Board of Directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances the Board of Directors deemed relevant in determining their independence.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit and All Other Fees

The following table presents the fees billed to us for professional services related to the years ended December 31, 2014 and 2013 by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global:

	2014	2013
Audit Fees[1]	$ 162,000	$ 154,000
Audit-Related Fees[2]	40,000	-
Tax Fees[3]	-	-
All Other Fees[4]	-	-
Total	$ 202,000	$ 154,000

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

Our audit committee has considered whether the provision of non-audit services is compatible with maintaining the independence of Kost Forer Gabbay & Kasierer and has concluded that the provision of such services is compatible with maintaining the independence of our auditors.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the audit committee. These services may include audit services, audit- related services, tax services and other services. Our audit committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our auditors. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by our independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements and Schedules

(a)

The following documents are filed as part of this report:

(1) Financial Statements:

CELSUS THERAPEUTICS PLC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2014

U.S. DOLLARS IN THOUSANDS

INDEX

(2) Financial Statement Schedules:

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

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

SIGNATURES

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

Date: February 11, 2015

By: **Celsus Therapeutics Plc**
/s/ Gur Roshwalb
Gur Roshwalb
Chief Executive Officer

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

Signature	Title	Date
/s/ Gur Roshwalb Gur Roshwalb	Chief Executive Officer and Director (Principal Executive Officer)	February 11, 2015
/s/ Dov Elefant Dov Elefant	Chief Financial Officer (Principal Financial and Accounting Officer)	February 11, 2015
/s/ Mark S. Cohen Mark S. Cohen	Executive Chairman of the Board of Directors	February 11, 2015
/s/ David Sidransky David Sidransky	Director	February 11, 2015
/s/ Johnson Yiu-Nam Lau Johnson Yiu-Nam Lau	Director	February 11, 2015
/s/ Amos Eiran Amos Eiran	Director	February 11, 2015
/s/ Robert F. Doman Robert F. Doman	Director	February 11, 2015
/s/ Allan Shaw Allan Shaw	Director	February 11, 2015

Kost Forer Gabbay & Kasierer
3 Aminadav St.
Tel-Aviv 6706703, Israel

Tel: +972-3-6232525
Fax: +972-3-5622555
ey.com

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

CELSUS THERAPEUTICS PLC.

We have audited the accompanying consolidated balance sheets of Celsus Therapeutics PLC. (the "Company") and its subsidiaries as of December 31, 2014 and 2013, and the related consolidated statement of operations, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above, present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of December 31, 2014 and 2013, and the consolidated results of their comprehensive loss and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

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

Tel-Aviv, Israel
February 11, 2015

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	December 31,	
	2014	**2013**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 6,216	$ 7,657
Short term restricted deposit	142	-
Accounts receivable and prepaid expenses	73	175
Total current assets	6,431	7,832
PROPERTY AND EQUIPMENT, NET (Note 3)	49	-
Total assets	$ 6,480	$ 7,832

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	December 31,	
	2014	**2013**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,003	$ 652
Other accounts payable (Note 5)	356	579
Total current liabilities	1,359	1,231
LONG-TERM LIABILITIES:		
Liability related to stock options and warrants	235	787
Other long term liabilities	33	-
Total long-term liabilities	268	787
COMMITMENTS AND CONTINGENT LIABILITIES (Note 6)		
SHAREHOLDERS' EQUITY (Note 7):		
Ordinary shares of £ 0.01 par value - Authorized: 5,000,000,000 shares at December 31, 2014 and 2013; Issued and outstanding: 55,636,283 and 40,227,953 shares at December 31, 2014 and 2013, respectively	927	675
Additional paid-in capital	34,116	25,681
Accumulated deficit	(30,190)	(20,542)
Total shareholders' equity	4,853	5,814
Total liabilities and shareholders' equity	$ 6,480	$ 7,832

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,		
	2014	**2013**	**2012**
Research and development expenses	$ 6,417	$ 1,276	$ 1,483
General and administrative expenses	3,760	2,330	2,184
Operating loss	10,177	3,606	3,667
Financial (income) expense, net (Note 10)	(529)	14	601
Net loss	$ 9,648	$ 3,620	$ 4,268
Deemed dividend related to warrants modification	-	-	33
Net loss attributable to holders of ordinary shares	$ 9,648	$ 3,620	$ 4,301
Net basic and diluted loss per share	$ (0.18)	$ (0.17)	$ (0.35)
Weighted average number of ordinary shares used in computing basic net loss per share	54,116,557	21,075,065	12,458,874
Weighted average number of shares of ordinary shares used in computing diluted net loss per share	54,271,330	21,075,065	12,458,874

The accompanying notes are an integral part of the consolidated financial statements.

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Additional paid in capital	Receipts on account shares	Accumulated Deficit	Total
	Number	Amount				
Balance as of December 31, 2011	12,098,597	$ 225	$ 9,836	$ 75	$ (12,621)	$ (2,485)
Issuance of share capital, net ($ 1.32-$ 1.94 per share)	1,254,933	20	1,992	(75)	-	1,937
Share based compensation	-	-	450	-	-	450
Issuance of shares granted to service provider	16,279	*) -	25	-	-	25
Expiration of deferred shares	-	-	128	-	-	128
Classification of warrants from liability to equity as a result of modification	-	-	35	-	-	35
Classification of warrants from liability to equity as a result of expiration of most favored nation terms	-	-	141	-	-	141
Conversion of trade payables into warrants	-	-	309	-	-	309
Beneficial conversion feature related to convertible notes	-	-	250	-	-	250
Receipts on account of shares				118		118
Deemed dividend related to warrants' modification	-	-	33	-	(33)	-
Net loss	-	-	-	-	(4,268)	(4,268)
Balance as of December 31, 2012	13,369,809	$ 245	$ 13,199	$ 118	$ (16,922)	$ (3,360)
Issuance of share capital and warrants, net ($ 2.00)	853,150	14	1,160	(118)	-	1,056
Issuance of share capital, net ($ 0.57 per share)	21,958,302	352	11,265	-	-	11,617
Classification of warrants from liability to equity as a result of investors exercise of most favored nation terms	407,673	6	21	-	-	27
Issuance of shares due to price protection provision	3,639,019	58	(58)	-	-	-
Share based compensation	-	-	94	-	-	94
Net loss	-	-	-	-	(3,620)	(3,620)
Balance as of December 31, 2013	40,227,953	675	25,681	-	(20,542)	5,814
Issuance of share capital, net ($ 0.60)	15,333,330	250	7,969	-	-	8,219
Issuance of shares to service provider	75,000	2	54	-	-	56
Share based compensation	-	-	412	-	-	412
Net loss	-	-	-	-	(9,648)	(9,648)
Balance as of December 31, 2014	55,636,283	$ 927	$ 34,116	$ -	$ (30,190)	$ 4,853

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2014	**2013**	**2012**
Cash flows from operating activities:			
Net loss	$ (9,648)	$ (3,620)	$ (4,268)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share based compensation and issuance of shares granted to service provider	468	94	514
Depreciation	8	2	2
Changes in values of deferred shares and liability related to stock options and warrants	(552)	(286)	(418)
Decrease (increase) in accounts receivable and prepaid expenses	102	(161)	7
Increase (decrease) in trade payables	351	(1,045)	627
Increase (decrease) in other accounts payable	(223)	(676)	394
Increase in other long term liabilities	33	-	-
Accrued interest expenses and issuance costs	-	242	1,008
Net cash used in operating activities	(9,461)	(5,450)	(2,134)
Cash flows from investing activities:			
Purchase of property and equipment	(57)	-	-
Investment in short term restricted deposit	(142)	-	-
Net cash used in investing activities	(199)	-	-
Cash flows from financing activities:			
Proceeds from issuance of shares and warrants, net	8,219	13,103	2,224
Proceeds from issuance of convertible notes and warrants, net	-	-	890
Repayment of convertible notes	-	(1,100)	-
Receipts on account of shares	-	-	118
Net cash provided by financing activities	8,219	12,003	3,232
Increase (decrease) in cash and cash equivalents	(1,441)	6,553	1,098
Cash and cash equivalents at the beginning of the period	7,657	1,104	6
Cash and cash equivalents at the end of the period	$ 6,216	$ 7,657	$ 1,104

The accompanying notes are an integral part of the consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 1:- GENERAL

a. Celsus Therapeutics PLC (the "Company"), was incorporated in Great Britain as a private limited company and commenced business operations on October 7, 2004. On February 15, 2005 the Company was registered as a non-traded public company under the laws of England and Wales. The Company is engaged in the development of ethical synthetic drugs for the treatment of inflammatory conditions such as atopic dermatitis, etc. The Company listed its securities on the NASDAQ Capital Market in January 2014.

b. On January 28, 2005 the Company acquired Morria Biopharmaceuticals Inc. (the "Subsidiary"), now Celsus Therapeutics Inc. The Subsidiary was the owner of the intellectual property rights in drugs which it develops under a license that was granted by Yissum, the research development company of the Hebrew University of Jerusalem Israel ("Yissum") on November 27, 2002, and in connection with which a sublicense agreement was signed between the Subsidiary and the Company on February 1, 2005 (for details about the license agreement with Yissum Note 6).

c. On March 22, 2011 the Company established an Israeli subsidiary, Morria Biopharma Ltd., which is wholly-owned by the Company. As of the date of the financial statements, this Israeli subsidiary is inactive.

d. The Company depends on third-party suppliers for the raw materials required for the production of its product candidates. The Company also does not have the ability to independently conduct clinical trials for its drug candidates, and it relies on third parties, such as contract research organizations, medical institutions, and clinical investigators to perform this function.

e. As of December 31, 2014, the Company has accumulated losses in the total amount of $ 30,190 and has negative cash flow from operating activity in 2014 in the total amount of $ 9,461.

The Company is addressing its liquidity needs by implementing initiatives to raise additional funds as well as other measures that will allow it to cover its anticipated budget. The Company is currently conducting a Phase II clinical trial for its lead clinical candidate, but has no assurance of positive results. In case of positive results, the Company will have to obtain additional capital resources to continue to fund additional clinical trials.

There are no assurances that the Company will be successful in obtaining an adequate level of financing needed for its long-term research and development activities. In any case, if the Company is unable to raise sufficient capital resources, the Company will not be able to continue the development of all of its products or may be required to delay part of the development programs and significantly reduce its activity in order to maintain its operations at least through December 31, 2015.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements were prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP").

a. Use of estimates:

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. The Company's 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.

b. Financial statements in United States dollars:

Most of the Company's costs and financing are in U.S. dollars ("Dollar"). The Company's management believes that the Dollar is the currency of the primary economic environment in which the Company and its subsidiaries have operated and expect to continue to operate in the foreseeable future. Therefore, the functional currency of the Company and its subsidiaries is the Dollar.

The Company and its subsidiaries' transactions and balances denominated in Dollars are presented at their original amounts. Non-Dollar transactions and balances have been remeasured to Dollars in accordance with ASC 830, "Foreign Currency Matters". All transaction gains and losses from remeasurement of monetary balance sheet items denominated in non-Dollar currencies are reflected in the statements of income as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash equivalents:

Cash equivalents are short-term unrestricted highly liquid investments that are readily convertible into cash, with original maturities of three months or less at acquisition.

e. Short term restricted deposit:

Short term restricted deposit are investments held as collateral for a letter of credit related to the Company’s office lease.

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

f. 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

g. Impairment of long-lived assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant, and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. During the years ended December 31, 2014, and 2013 no impairment losses have been identified.

h. Research and development costs:

Research and development expenses, consist of independent research and development costs of third parties services and license fees to third parties. All such costs are expensed as incurred.

i. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company implements a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement. As of December 31, 2014 and 2013, the Company does not hold provision for uncertain tax positions.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents.

The Company's cash and cash equivalents are invested in deposits mainly in Dollar and British Pound with major international banks. Generally, these deposits may be redeemed upon demand and therefore bear minimal risk.

k. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of ordinary shares, par value $ 0.01 per share outstanding during each period. Diluted net loss per share is computed based on the weighted average number of ordinary shares outstanding during each period, plus dilutive potential ordinary shares considered outstanding during the period, in accordance with ASC topic 260, "Earnings Per Share" ("ASC 260").

The total weighted average number of shares related to the outstanding warrants and options excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 4,548,580, 3,233,391 and 2,053,817 for the years ended December 31, 2014, 2013 and 2012, respectively. The total number of shares related to conversion rights of the deferred shares excluded from the calculations of diluted net loss per share was 0, 0 and 180,822 for the years ended December 31, 2014, 2013 and 2012, respectively. As of June 13, 2012 all of the deferred shares were expired.

l. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation," which requires 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 date of grant 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 the Company's consolidated statement of comprehensive loss.

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The Company recognizes compensation expenses for the value of its 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.

The Company selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the most appropriate fair value method for its stock-option awards and values stock based on the market value of the underlying shares at the date of grant. The Company estimates the fair value of stock options granted with the following weighted-average assumptions for 2014, 2013 and 2012:

	December 31,		
	2014	2013	2012
Risk-free interest rate	0.7%-2.17%	0.45%-1.75%	0.69%-1.78%
Expected volatility	61.2%-81.7%	67.4%-85.55%	78.9%-89.99%
Expected life (in years)	2.7-10.0	3.7-6.25	4.5-10.0
Expected dividend yield	0%	0%	0%

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 the Company's historical experience and expectation of no future dividend payouts. The Company has historically not paid cash dividends and has no foreseeable plans to pay cash dividends in the future.

The Company applies ASC 718 and ASC 505-50, "Equity-Based Payments to Non-Employees" with respect to options, warrants and deferred shares issued to non-employees. ASC 718 requires the use of option valuation models to measure the fair value of the options, warrants and deferred shares at the measurement date. Since the exercise price of some of the options is denominated in a currency that is different from the Company's functional currency, the Company accounts for such options as a liability (for details about the options denominated in a different currency Note 7e).

m. Fair value of financial instruments:

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The carrying amounts of cash and cash equivalents, accounts receivable and prepaid expenses, trade payables and other accounts payable approximate their fair value due to the short-term maturity of such instruments.

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

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

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

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

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

n. Derivative instruments:

As of balance sheet date, none of the Company's derivatives qualify for hedge accounting under ASC 815, "Derivatives and Hedging" ("ASC 815"). All of the Company's derivative instruments are warrants related to equity financing rounds which occurred during 2012 and 2013 (for further information see Note 7c). Consequently, all derivatives 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 financial income or expenses.

During the years ended December 31, 2014, 2013 and 2012, the Company recorded a net gain from derivatives transactions in the amount of $ 549, $ 270 and $ 418, respectively.

o. Impact of recently issued Accounting Standards :

In June, 2014, the FASB issued ASU 2014-101 (“Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in ASC Topic 810, Consolidation”) to eliminate the concept of a development stage entity (“DSE”) from U.S. GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs and is intended to result in cost-savings for affected entities, such as certain start-up or research and development entities. In addition, ASU 2014-10 introduces new disclosure requirements about the reporting entity’s risks and uncertainties. ASU 2014-101 is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. The Company elected early adoption as of June 30, 2014 and does not believe the adoption of the standard had a material impact on its financial position, comprehensive loss or related financial statement disclosures.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

NOTE 3:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2014	**2013**
Cost:		
Computers, peripheral and scientific equipment	$ 10	$ 9
Office furniture and equipment	57	1
	67	10
Accumulated depreciation:		
Computers, peripheral and scientific equipment	(9)	(9)
Office furniture and equipment	(9)	(1)
Depreciated cost	$ 49	$ -

Depreciation expense for the years ended December 31, 2014 and 2013 was $ 8 and $ 2, respectively. In 2013 the Company disposed of property and equipment in amount of $ 3.

NOTE 4:- FAIR VALUE MEASURMENTS

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. Investments in foreign currency derivative instruments are classified within Level 3 value hierarchy. This is because these assets are valued using alternative pricing sources and models utilizing market observable inputs. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 4:- FAIR VALUE MEASURMENTS (Cont.)

The Company considers an active market to be one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis, and views an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. Since in prior years, the quoted market value of the Company's ordinary shares was based on a sporadically traded stock with little or no volume, the Company's management determined the Company's share price fair value based on ASC 820 Fair Value Measurement using the market approach assisted by a third party specialist. Following the Company's uplist to NASDAQ in January 2014, management considers share price value in an active market and determined fair value of ordinary shares based on the closing price in the market.

In previous years, the Company issued to its investors a package that included shares and warrants with certain terms and conditions such as anti dilution rights. The Company isolated the value of the warrants and anti dilution rights from the ordinary share value, in order to determine the stand-alone fair value of the ordinary shares. For this purpose it was necessary to calculate the fair value of the warrants, including its anti dilution rights. This was performed by calculating numerous iterations in the Black-Scholes option pricing model.

Consequently, the Company used the estimated share price fair value in the underlying assumptions of the computation of the fair value of the liability related to stock based compensation and warrants. As of December 31, 2014 and 2013, the fair value liability related to stock based compensation and warrants using input type Level 3 were $ 235 and $ 787, respectively.

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:

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

Balance at December 31, 2012	$	630
Fair value of warrants at issuance date		471
Classification of warrants from liability to equity as result of investors exercise of the Most Favored Nation Terms (See Note 9b)		(28)
Changes in values of liability related to stock option and warrants		(286)
Balance at December 31, 2013		787
Changes in values of liability related to stock option and warrants		(552)
Balance at December 31, 2014	$	235

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 5:- OTHER ACCOUNTS PAYABLE

	December 31,	
	2014	2013
Accrued expenses	$ 352	$ 403
Employees	4	176
	$ 356	$ 579

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES

a. Agreement with Yissum:

On November 27, 2002, the Subsidiary executed a license agreement with Yissum, pursuant to which the Subsidiary was granted a global, exclusive license, including the right to grant sublicenses, subject to receipt of the prior written approval of Yissum which shall not be unreasonably withheld. The full intellectual property rights concerning the technology subject to the license are and will remain fully owned by Yissum for the licensed technology developed by Yissum.

This technology underlies part of the Company's research and development projects. The license includes the exclusive rights to produce, sell, market, import, distribute, and make any use of the technology, by both the Subsidiary and the holders of rights by virtue of the sublicenses. The agreement is valid for 20 years or until the last to expire patent. In exchange for granting the said license to the Subsidiary, Yissum will be entitled to royalties as elaborated below:

1. 4% of the total sales that the Subsidiary or a related company thereof (as this term is defined in the agreement) will make;

2. 18% of the total payments or royalties that Subsidiary will be entitled to receive from third parties to whom sublicenses have been granted.

On June 20, 2005, the Company executed with Yissum an agreement for providing research and development services, whereby Yissum grants the Company compound development services. It has been agreed that the intellectual property and the knowledge that will accumulate during the provision of the services will be owned by Yissum.

Yissum has granted the Company a license to use the results of the service provision agreement, and the permission to grant a sublicense. The service agreement was renewed several times prior to 2011. On February 28, 2011, the service provision agreement was renewed again. In consideration for the performance of services the Company agreed to pay Yissum up to $ 70 plus overhead per year, depending on the work requested by the Company to be done at the sole and exclusive option of the Company during each year of the following five years. The additional services fees shall be payable in semi-annual payments. During the years ended December 31, 2014, 2013 and 2012 the Company recorded $ 0, $ 0 and $ 70, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

b. Office lease commitment:

The following table summarizes the future minimum lease payable under non-cancelable operating lease of the next five years, and therafter, as of December 31, 2014:

Year-ended December 31,		Total
2015	$	289
2016		297
2017		313
2018		330
2019 and thereafter		225
Total	$	1,454

The Company entered into a five year lease for offices in the United States with total minimum rental commitments of approximately $ 1,561. The lease expires in August 2019. The Company's registered address is located in Great Britain with minimum rental commitments of approximately $ 0.5 plus VAT for each month. The Agreement commenced on February 1, 2010, and shall continue until it is terminated by either party giving the other three months' prior written notice.

NOTE 7:- SHAREHOLDERS' EQUITY

a. Composition of share capital:

	December 31, 2014		December 31, 2013	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
Ordinary shares of £ 0.01 par value each	5,000,000,000	55,636,283	49,800,000	40,227,953
Deferred A shares of £ 0.001 par value	800,000	-	800,000	-
Deferred B shares of £ 0.001 par value	1,200,000	-	1,200,000	-
Deferred C shares of £ 0.001 par value	400,000	-	400,000	-

The ordinary shares confer upon their holders the right to participate and vote in general shareholders meetings of the Company and to share in the distribution of dividends, if any, declared by the Company.

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

b. Shares issuances:

During 2012, the Company issued 1,271,212 ordinary shares of £ 0.01 par value each. The total proceeds amounted to $ 2,447, net of $ 75 included in receipt on account of shares (the "2012 Purchase Agreements"). As part of the share issuance, the Company granted warrants to purchase 1,269,164 ordinary shares at exercise prices of $ 1.72 - $ 2.25. The warrants are subject to certain provisions such as price protection and most favored nation terms as defined in Note 7c.

On September 24, 2013, the Company closed a securities purchase agreement with certain institutional accredited investors, pursuant to which it agreed to sell, in a private placement, an aggregate of 21,958,302 ordinary shares for an aggregate purchase price of $ 12,516 (the "September 2013 Financing"). The issuance costs in relation to the September 2013 Financing were $ 898.

In February 2014, the Company completed a public offering of its shares on NASDAQ. The Company issued 15,333,300 of its ordinary shares, nominal value £ 0.01 per share at a price of $ 0.60 per share before issuance expenses. Total net proceeds from the issuance amounted to approximately $ 8,219, net of issuance expenses in the amount of $ 981.

Also in February 2014, the Company issued 75,000 of its ordinary shares, nominal value £ 0.01 per share to a service provider. As part of this transaction the Company recorded compensation expense of $ 56 to general and administrative expenses.

c. Warrants issued in connection with the finance arrangements:

Under the terms of the 2012 Purchase Agreements, from the date each investor entered into the agreement until (i) the two year anniversary of the effective date of a registration statement (which will be April, 2015) or (ii) the date immediately following the 20 consecutive trading days wherein the trading volume for the Ordinary Shares or ADSs exceeds $ 100 per trading day, each investor may elect to exchange all of its shares and warrants for any such additional securities issued by the Company in a subsequent financing (as defined in the 2012 Purchase Agreements), on the same terms and conditions as provided to the investors in a subsequent financing on a $ 1 for $ 1 basis, in lieu of cash consideration (the "Most Favored Nation Terms").

From January 17, 2013 through September 17, 2013, the Company completed several private placements by and among the Company and certain investors. As part of the financings, the Company sold an aggregate of 853,150 ordinary shares at $ 2.00 per share and 989,075 warrants, for gross proceeds of $ 1,706. The warrants and the shares are eligible Most Favored Nation Terms and also to price protection. Under the terms of the Agent Agreement (as defined in Note 7e5), the Company issued 10,800 warrants with an exercise price of $ 2.00 per share and a contractual life of five years.

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

As a result of the September 2013 Financing, several investors have utilized their rights for Most Favored Nations Terms provision and subsequently the Company issued 407,673 additional ordinary shares and an amount of 81,250 warrants expired. Additionally, due to the September 2013 Financing, and as a result of price protection provisions from investment agreements with previous investors, (i) an aggregate of 3,639,019 additional ordinary shares were issued to previous investors, and (ii) there will be an additional 1,259,092 ordinary shares issuable upon exercise of outstanding warrants since the exercise price of certain warrants issued in the 2012 Purchase Agreements was reduced to $ 0.57 per share, in accordance with the anti-dilution provisions contained in the 2012 Purchase Agreements.

As of December 31, 2014 the Company had 5,659,717 shares which are entitled to Most Favored Nations Terms, of which 5,089,544 area also entitled to price protection (which would be triggered by a share issuance at less than $ 0.57 per share). In addition, 729,450 warrants which are entitled to price protection (which would be triggered by a warrant issuance at less than $ 2.00 exercise price per share) and 1,929,824 warrants have full ratchet anti-dilution protection (which would be triggered by a warrant issuance at less than $ 0.57 exercise price per share).

In relation to the share issuances in 2012 and 2013 before the September 2013 Financing, the Company first allocated the proceeds to the detachable warrant, that due to the Most Favored Nation Terms and in accordance with ASC 815 is being considered 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 statement of comprehensive loss as financial income or expense. The remaining proceeds were allocated to the shares and were recorded to equity. The issuance costs were allocated between the warrants and the shares in proportion to the allocation of the proceeds. The portion of the issuance costs that were allocated to the warrants was recorded as financial expense in the Company's statement of comprehensive loss. The portion of the issuance costs that were allocated to the shares was recorded to additional paid in capital.

The fair value of warrants granted was valued by using the Black-Scholes call option pricing model. The anti-dilution adjustments of Most Favored Nation Terms were calculated using Black-Scholes put option model since its similar to put options by providing a guaranteed price for an underlying instrument and offer insurance against dilution.

The Company used different parameters for the warrants call option and the warrants put option since the expected life of the Most Favored Nation Terms was shorter than the expected life of the warrants. Fair values were estimated using the following assumptions for the warrants call option (range of annualized percentages):

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

	December 31, 2014	December 31, 2013
Dividend yield	0%	0%
Expected volatility	59%	85%
Risk-free interest	0.28%	0.41%
Expected life	1.0 years	2.1 years

Fair values were estimated during 2014 and 2013 using the following assumptions for the warrants put option (range of annualized percentages):

	December 31, 2014	December 31, 2013
Dividend yield	0%	0%
Expected volatility	56%	88%
Risk-free interest	0.1%	0.2%
Expected life	0.3 years	1.3 years

d. Share option plan:

In August 2007, the Company adopted a share option 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 1,365,000 shares. In June 2013, the Plan was amended increasing the number of shares that may be issued by 2,500,000 to a total of 3,865,000. In June 2014, the Company adopted a new equity incentive plan (the “2014 Plan”) which assumed all shares under the Plan and also increased the number of shares that may be issued by 2,000,000 to a total of 5,865,000. As of December 31, 2014, 2,873,310 ordinary shares are available for future issuance under the 2014 Plan.

The following is a summary of the Company's stock option activity related to employees and directors and related information for the period ended December 31, 2014 and 2013:

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

	Amount of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Balance as of December 31, 2012	770,527	$ 1.44	7.2	$ 169
Granted	1,570,000	$ 1.82		
Expired	(137,300)	$ 1.51		
Balance as of December 31, 2013	2,203,227	$ 1.71	8.6	$ -
Granted	845,000	$ 0.70		
Forfeited	145,000	$ 1.61		
Balance as of December 31, 2014	2,903,227	$ 1.42	8.0	$ -
As of December 31, 2014				
Vested and expected to vest options	2,903,227	$ 1.42	8.0	$ -
Exercisable Options	1,490,727	$ 1.39	7.2	$ -

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's stock price on December 31, 2014 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on the last trading day of the fiscal year. This amount changes based on the fair market value of the Company's shares.

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

Exercise price (range) $	Options outstanding as of December 31, 2014	Weighted average remaining contractual life (years)	Weighted average exercise price $	Options exercisable as of December 31, 2014	Remaining contractual life (years for exercisable options	Weighted average exercise price $
0.57-0.75	1,000,000	9.17	0.67	422,500	9.08	0.74
1.23-1.56	618,227	4.84	1.39	618,227	4.84	1.39
2.00	1,285,000	8.72	2.00	450,000	8.69	2.00
	2,903,227			1,490,727		

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

During the year ended December 31, 2014, the Company recorded $ 412 in share based compensation expenses. As of December 31, 2014, total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Company's stock option plans was $ 313. That cost is expected to be recognized over a weighted-average period of 2.55 years.

e. Options and warrants to service providers:

The options and warrants outstanding as of December 31, 2014 that were granted to the Company's service providers are as follows:

Grant date	Number of options	Exercise Price	Expiration date
August 28, 2007 (1)	20,475	1.29	August 28, 2017
May 27, 2009 (1)	30,000	1.56	May 27, 2019
February 12, 2012 (2)	309,492	2.00	February 12, 2017
April 26, 2012 (3)	90,000	2.00	March 19, 2017
June 27, 2012 (4)	2,988	1.75	June 21, 2022
November 30, 2012 (5)	90,180	2.00	November 30, 2017
August 27, 2014 (6)	35,000	0.57	August 27, 2024
	578,135		

1. In 2007 and 2009, the Company granted 20,475 and 30,000 fully vested options, respectively, to the pre-clinical development consultant. The fair value of the options was $ 29 (unaudited) and $ 33, respectively. Since the exercise price of such options is denominated in a currency that is different from the Company's functional currency, the Company accounts for such options as a liability. The fair value of the options was estimated each cut-off date using the Black-Scholes options valuation model.

   The changes in fair value were recorded as financial expense (income). The Company recorded financial income in the amount of $ 2 and $ 20 for the years ended December 31, 2014 and 2013, respectively.

2. On February 12, 2012, the Company settled part of an outstanding debt to a related party by issuance of fully vested warrants to purchase 309,492 ordinary shares, £ 0.01 par value each.

3. In 2011, the Company granted 35,000 fully vested warrants to an independent contractor (the "Finder") under a consulting agreement that was signed in 2011 ("2011 Consulting Agreement"). The exercise price was $ 1 and the contractual life is five years. The fair value of the warrants in the amount of $ 45 was recorded to additional paid-in capital. In the months January and February 2012, the Company granted additional 10,000 fully vested warrants to the Finder under the 2011 Consulting Agreement. The exercise price was $ 1 per share and the contractual life is five years. The fair value of the warrants in the amount of $ 12 was recorded to additional paid-in capital.

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

In April 2012, the Company modified the amount of warrants that were granted to the Finder from a total of 45,000 warrants to 90,000 warrants and also modified the exercise price from $ 1 to $ 2. The Company accounted for these changes as modifications in accordance with ASC 718. The Company calculated the incremental value of these modifications and recorded compensation cost in a total amount of $ 38 to additional paid-in capital.

4. On June 27, 2012, the Company granted 2,988 options which shall vest on December 27, 2012. The Company recorded compensation expense in the amount of $ 2 in the statement of comprehensive loss during the year ended December 31, 2012.

5. On August 23, 2012, the Company entered into an agreement with an agent (the "Agent") to advise the Company on a private placement offering and as a contact with potential financing sources for the Company (the "Agent Agreement"). The Company agreed to pay the Agent a cash transaction fee in the amount of between 7% - 8% of the amount of the financing; and warrants equal to 7% - 8% of the stock and warrants issued in the financing at an exercise price equal to the investor's warrant exercise price. The consideration that is paid to the Agent is treated as issuance expenses. Pursuant to the terms of the Agent Agreement, the Company issued 90,180 warrants and paid $ 120 in cash, for advisory services in relation with the 2012 Purchase Agreements.

6. On August 27, 2014, the Company granted 35,000 options which shall vest in August 2015 and 2016, equally . The Company recorded compensation expense in the amount of $ 2 in the statement of comprehensive loss during the year ended December 31, 2014.

The share based expense recognized in the financial statements for services received from employees and non-employees is shown in the following table:

	Year ended December 31,		
	2014	2013	2012
Research and development	$ 24	$ (18)	$ (2)
General and administrative expenses	386	92	469
Financial (income), net	-	-	(82)
	$ 410	$ 74	$ 385

NOTE 8:- TAXES ON INCOME

a. Tax rates:

The Company is incorporated in Great Britain. The corporate tax rate applying to a company that is incorporated in Great Britain December 31, 2014 is 21.50%, reduced from 23.25% from December 31, 2013. For companies with taxable income of less than £ 300,000 and having no related companies the corporate tax rate is 20%. The Subsidiary is incorporated in the United States. The corporate tax applying to a company that is incorporated in the United States consists of a progressive corporate tax at a rate of up to 34% plus state tax and local tax at rates depending on the state and the city in which the company manages its business. In the Company's estimation, it is subject to approximately a 40% tax rate.

b. Tax assessment:

The Company has final tax assessment in Great Britain through 2011. The Subsidiary has not been issued final tax assessments since its establishment.

c. Net operating losses carryforward:

As of December 31, 2014, the Company's net operating losses carryforward for tax purposes in Great Britain amounted to approximately $ 6,544. These net operating losses may be carried forward indefinitely and may be offset against future taxable income. The Company expects that during the period in which these tax losses are utilized its income will be substantially tax-exempt.

The Subsidiary is subject to U.S. income taxes. As of December 31, 2014, the Subsidiary has net operating loss carry-forward for federal and state income tax purposes of approximately $ 54 which expires in the years 2018-2029. Utilization of the U.S. net operating losses may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions.

The annual limitation may result in the expiration of net operating losses before utilization.

d. Deferred taxes:

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

NOTE 8:- TAXES ON INCOME (Cont.)

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

f. The Company carries out extensive research and development activities, and may benefit from the United Kingdom research and development tax credit regime, whereby the Company is able to surrender a portion of trading losses that arise from its research and development activities for a refundable credit of eligible research and development expenditures.

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

In December 2014, the Company for the first time filed a credit claim for tax years 2013 and 2012. The credit claim is in the amount of £ 155,795 (or $ 242) and £ 207,548 (or $ 322) for the year ended 31 December 2013 and 2012, respectively. Due to the uncertainty of the approval of these tax credit claims, the Company did not a record a related receivable as of December 31, 2014.

NOTE 9: - RELATED PARTIES

a. The Chairman of the Company's board of directors is a senior partner in the law firm which represents the Company in intellectual property and commercial matters (the "Service Provider"). The Service Provider charges the Company for services it renders on an hourly basis. The trade payable balances were $ 118 and $ 330, respectively as of December 31, 2014 and 2013 and transactions with Service Provider charged to general and administrative expense were $ 749, $ 555 and $ 365, respectively as of December 31, 2014, 2013 and 2012.

In February 2012 the Company settled part of its outstanding debt to a related party by issuance of fully vested warrants, (for details about the issuance Note 7e2).

b. As part of an agreement of the Company with one of its members of the board of directors signed in May 2011, the Company recorded an expense amounting to $ 66 in 2013 for services provided by the director in his position as Chief Scientific Officer. During December 2013 the director resigned as Chief Scientific Officer and the $ 66 was subsequently paid in January 2014.

U.S. dollars in thousands (except share and per share data)

NOTE 10:- FINANCIAL EXPENSES (INCOME), NET

	Year ended December 31,		
	2014	2013	2012
Financial expenses:			
Interest expense due to amortization of convertible notes	$ -	$ 202	$ 898
Issuance expenses	-	40	137
Others	20	42	6
	20	284	1,041
Financial income:			
Changes in values of deferred shares and liability related to stock options and warrants	(549)	(270)	(418)
Others	-	-	(22)
	(549)	(270)	(440)
	$ (529)	$ 14	$ 601

Exhibit List

Exhibit No.	Exhibit Description
3.1*	Celsus Therapeutics Plc, Memorandum of Association
3.2*	Celsus Therapeutics Plc, New Articles of Association
4.1##	Form of Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder
4.2§§§	Amendment to Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder
4.3##	Form of American Depositary Receipt; the Form is Exhibit A of the Form of Amendment to the Deposit Agreement
4.4**	Form of April 2012 Warrant
4.5##	Form of Warrant dated November 30, 2012
4.6#	Form of Series A Warrant dated January 17, January 31 and February 28, 2013
4.7#	Form of Series B Warrant dated January 17, 2013
4.8#	Form of Series C Warrant dated January 17, 2013
4.9#	Form of Series GSS Warrant dated January 17, January 31 and February 28, 2013
10.1*	Exclusive License Agreement, dated as of November 27, 2002, by and between Morria Biopharmaceuticals, Inc. and Yissum Research Development Company of the Hebrew University of Jerusalem
10.3*	Extension Agreement for Rendering of Services, dated as of June 20, 2006, by and between the Registrant and Yissum Research Development Company of the Hebrew University of Jerusalem
10.4*	Second Extension Agreement for Rendering of Services, dated as of December 19, 2006, by and between the Registrant and Yissum Research Development Company of the Hebrew University of Jerusalem
10.5*	Third Extension Agreement for Rendering of Services, dated as of June 17, 2007, by and between the Registrant and Yissum Research Development Company of the Hebrew University of Jerusalem
10.6*	Fourth Extension Agreement for Rendering of Services, dated as of May 6, 2008, by and between the Registrant and Yissum Research Development Company of the Hebrew University of Jerusalem
10.7*	Fifth Extension Agreement for Rendering of Services, dated as of February 22, 2011, by and between the Registrant and Yissum Research Development Company of the Hebrew University of Jerusalem
10.8**	Director Agreement, dated as of June 16, 2005, between the Registrant and Gilead Raday
10.9**	Amendment to Director Agreement, dated as of March 14, 2007, between the Registrant and Gilead Raday
10.10**	Chairman Agreement, dated as of February 18, 2005, between the Registrant and Mark Cohen
10.11**	Director Agreement, dated as of August 28, 2007, between the Registrant and Dr. Johnson Lau
10.12**	Director Agreement, dated as of August 28, 2007, between the Registrant and Dr. David Sidransky
10.13**	Director Agreement, dated as of February 21, 2005 between the Registrant and Prof. Saul Yedgar

10.14*	Amendment to Director Agreement, dated as of March 14, 2007, between the Registrant and Prof. Saul Yedgar
10.15*	Employment Agreement, dated as of January 11, 2012, between Dov Elefant and the Registrant
10.16§§	Employment Agreement, dated as of October 23, 2013, between Dr. Pablo Jimenez and the Registrant
10.17*	Amended and Restated 2007 Stock Option Plan, dated April 26, 2012
10.18*	Second Amendment to Amended and Restated 2007 Stock Option Plan, dated June 20, 2012
10.19**	Securities Purchase Agreement dated April 3, 2012 by and between Morria Biopharmaceuticals Plc and the buyers listed on the Schedule of Buyers
10.20**	Sub-License Agreement dated February 1, 2005
10.21###	Form of Securities Purchase Agreement dated November 30, 2012 by and among Morria Biopharmaceuticals Plc and the buyers signatory thereto
10.22###	Registration Rights Agreement dated November 30, 2012 by and among Morria Biopharmaceuticals Plc and the Buyers signatory thereto
10.23#	Form of Securities Purchase Agreement dated January 17, January 31 and February 28, 2013, by and among Morria Biopharmaceuticals Plc and the buyers signatory thereto
10.24#	Registration Rights Agreement dated January 17, January 31 and February 28, 2013, by and among the Registrant and the Buyers signatory thereto
10.25#	Employment Agreement, dated as of March 4, 2013, between Gur Roshwalb, M.D. and the Registrant
10.26#	Form of Financing Subscription Agreement between the Registrant and Mark Cohen (including Form of Warrant) dated December 30, 2012
10.27#	Form of Financing Subscription Agreement between the Registrant and Mark Cohen (including Form of Warrant) dated January 31, 2013
10.28#	Form of Financing Subscription Agreement between the Registrant and Saul Yedgar (including Form of Warrant) dated April 3, 2013
10.29§	Form of Securities Purchase Agreement, dated as of September 19, 2013, by and among the Registrant and the purchasers named therein
10.30§	Form of Registration Rights Agreement, dated as of September 19, 2013, by and among the Registrant and the purchasers named therein
10.31**	Consulting Agreement, dated as of February 21, 2005, between the Registrant and Prof. Saul Yedgar
10.32**	Employment Agreement, dated as of May 25, 2011, between the Registrant and Prof. Saul Yedgar
10.33+	2014 Equity Incentive Plan
21.1*	List of subsidiaries
23.1	Consent of registered public accounting firm
31.1	Certification of Chief Executive Officer
31.2	Certification of the Chief Financial Officer
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema Linkbase Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Labels Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

*	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F (No. 000-54749) filed on June 28, 2012.
**	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F/A (No. 000-54749) filed on August 8, 2012.
***	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F/A (No. 000-54749) filed on September 27, 2012.
##	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form F-6 (No. 333-185197) filed on November 30, 2012.
###	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form F-1 (No. 333-185247) filed on December 3, 2012.
#	Incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement on Form F-1 (No. 333-185247) filed on March 22, 2013.
§	Incorporated by reference to the exhibit previously filed with the Registrant's Report of Foreign Private Issuer on Form 6-K filed on October 24, 2013.
§§	Incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form F-1 (No. 333-191880) filed on November 24, 2013.
§§§	Incorporated by reference to the registrant's Post-Effective Amendment No. 1 to Registration Statement on Form F-6 (No. 333-185197) filed on December 24, 2013.
+	Incorporated by reference to the exhibit previously filed with the Registrant's Report of Foreign Private Issuer on Form 6-K (No. 001-36288) filed on June 24, 2014.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form F-3 (No. 333-198107), the Registration Statement on Form S-8 (No. 333-198109) pertaining to the Stock Option Plan and Equity Incentive Plan of Celsus Therapeutics PLC and the Registration Statements on Post-Effective Amendments to Form F-1 on Form F-3 (Nos. 333-185247, 333-187826 and 333-191880) of our report dated February 11, 2015, with respect to the consolidated financial statements of Celsus Therapeutics PLC in this Annual Report on Form 10-K for the year ended December 31, 2014.

/s/ KOST FORER GABBAY & KASIERER
KOST FORER GABBAY & KASIERER
A Member of EY Global

Tel Aviv, Israel
February 11, 2015

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Gur Roshwalb, certify that:

1. I have reviewed this annual report on Form 10-K of Celsus 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: February 11, 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 annual report on Form 10-K of Celsus 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: February 11, 2015

/s/ Dov Elefant
Chief Financial Officer
Principal Financial Officer

Exhibit 32

CERTIFICATIONS UNDER SECTION 906

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

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 11, 2015

/s/ Gur Roshwalb
Chief Executive Officer
Principal Executive Officer

Dated: February 11, 2015

/s/ Dov Elefant
Chief Financial Officer
Principal Financial Officer