

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

FORM 20-F

(Mark One)

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

OR

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

OR

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

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission file number 001-36288

Celsus Therapeutics PLC
(Exact name of Registrant as specified in its charter)

The Laws of England and Wales
(Jurisdiction of incorporation or organization)

53 Davies Street, London, United Kingdom W1K 5JH
(Address of principal executive offices)

Mr. Mark S. Cohen
Executive Chairman
53 Davies Street
London W1K 5JH
United Kingdom

Telephone +44 20 3322 1321

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
American Depositary Shares, each representing 10 Ordinary Shares, par value £0.01 per share	The Nasdaq Capital Market
Ordinary Shares, £0.01 par value per share*	

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

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

The number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 40,227,953 Ordinary Shares, £0.01 par value per share**

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

** In addition, the Company has 633,333 Deferred B Shares, £0.001 par value per share, and 400,000 Deferred C Shares, £0.001 par value per share. All of such Deferred B and Deferred C Shares are outstanding but have expired and are no longer exercisable into Ordinary Shares.

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

Yes No

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

Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

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

Other

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

Item 17 Item 18

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

Yes No

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

Pursuant to the JOBS Act, we will remain an Emerging Growth Company until the earliest of:

- the last day of our fiscal year following the fifth anniversary of the date of our initial public offering of common equity securities;
- the last day of our fiscal year in which we have annual gross revenue of \$1.0 billion or more;
- the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; and
- the date on which we are deemed to be a “large accelerated filer,” which will occur at such time as we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months, and (c) have filed at least one annual report pursuant to the Exchange Act.

Celsus Therapeutics PLC

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FORWARD-LOOKING STATEMENTS

The Securities and Exchange Commission, or the SEC, encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This registration statement contains 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 preclinical 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.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this annual report might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this annual report. 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.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

A. Offer Statistics

Not applicable.

B. Method and Expected Timetable

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following selected consolidated financial data as of December 31, 2013 and 2012 and for the fiscal years ended December 31, 2013, 2012 and 2011 have been derived from our audited consolidated financial statements and notes thereto prepared in accordance with United States GAAP, or GAAP, included elsewhere in this Annual Report Form 20-F. The selected consolidated financial data as of December 31, 2010 and 2009 and for the fiscal year ended December 31, 2009 has been derived from our unaudited consolidated financial statements which are not included in this Annual Report Form 20-F. Our historical results are not necessarily indicative of results to be expected for future periods.

The selected consolidated financial data set forth below should be read in conjunction with, and are entirely qualified by reference to our audited consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this annual report.

	As of December 31,				
	2009	2010	2011	2012	2013
BALANCE SHEET DATA					
(In United States Dollars in \$000's)					
Total current assets	\$ 15	\$ 34	\$ 27	\$ 1,118	\$ 7,832
Total assets	15	34	27	1,120	7,832
Total current liabilities	805	1,222	2,236	3,850	1,231
Total liabilities	1,716	2,038	2,512	4,480	2,018
Working capital surplus (deficit)	(790)	(1,188)	(2,209)	(2,732)	6,601
Capital stock	213	216	225	245	675
Shareholders' equity (deficiency)	(1,701)	(2,004)	(2,485)	(3,360)	5,814

	As of December 31,				
	2009	2010	2011	2012	2013
INCOME STATEMENT DATA					
(In United States Dollars in \$000's, except for per share data)					
Research and development	\$ 159	\$ 247	\$ 841	\$ 1,483	\$ 1,276
General and administrative	449	545	1,406	2,184	2,330
Total operating expenses	608	792	2,247	3,667	3,606
Financial expense (income, net)	404	(117)	(128)	601	14
Net Loss	1,012	675	2,119	4,268	3,620
Net basic and diluted loss per share	\$ (0.09)	\$ (0.06)	\$ (0.18)	\$ (0.35)	\$ (0.17)
Weighted average number of Ordinary Shares	11,244,002	11,420,369	11,920,562	12,458,874	21,075,065

Year ended December 31,

	2009	2010	2011	2012	2013
OTHER FINANCIAL DATA					
(In United States Dollars in \$000's)					
Net cash used in operating activities	\$ (580)	\$ (366)	\$ (1,008)	\$ (2,134)	\$ (5,450)
Net cash provided by financial activities	499	372	1,005	3,232	12,003

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report Form 20-F, including our consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our Ordinary Shares or our ADSs. These material risks could adversely impact our results of operations, possibly causing the trading price of our Ordinary Shares and ADSs to decline, and you could lose all or part of your 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 \$3,620,000 and \$4,268,000 for the year ended December 31, 2013 and 2012, respectively, and \$2,119,000 and \$675,000 for the years ended December 31, 2011 and 2010, respectively. In addition, our accumulated deficit as of December 31, 2013 and December 31, 2012 was \$20,542,000 and \$16,922,000, respectively. We expect to continue to incur significant research and development and other significant operating expenses and capital expenditures and anticipate that we will continue to have significant expenses and losses in the foreseeable future as we:

- conduct our Phase 2 clinical trials of MRX-6 for dermatitis and initiate additional clinical trials, if supported by the results of such trials;
- conduct the synthesis and formulation of MRX-6;
- conduct preclinical toxicology and absorption, distribution, metabolism and excretion, or ADME, studies for MRX-6;
- conduct preclinical studies of OPT-1 for ophthalmic inflammation (including synthesizing and formulation of OPT-1);
- conduct preclinical studies of CFX-1 for cystic fibrosis (including synthesizing and formulation of CFX-1);
- Conduct preclinical work for other potential indications;
- expand our management;
- prepare and make filings with regulatory agencies, potentially including, but not limited to, IND filings with the FDA for MRX-6 and potentially OPT-1 and CFX-1; and
- incur increased general and administrative expenses as a result of being a public company.

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 regulatory applications 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 March 12, 2014, we had existing cash and investment securities of approximately \$14.0 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 2014 includes research and development expenses which includes personnel expenses, the synthesis, formulation and manufacturing and toxicology work of MRX-6 for its Phase II clinical trials as well as accounting, legal, personnel and corporate expenses to maintain our listing as a public company. In January through September 17, 2013, we received investments totaling \$1,706,000 and on September 24, 2013, we closed on investments totaling approximately \$12,516,000 that enabled us to continue the development of MRX-6 and prepare for our Phase II trial. Furthermore, on February 5, 2014, we closed on a public offering totaling approximately \$9,200,000. The additional capital raised enables us to initiate the following additional research and development activities:

- Conduct the formulation and toxicology testing of MRX-6 (in the approximate amount of \$2,900,000);
- Phase II clinical trials of MRX-6 for dermatitis (in the approximate amount of \$1,000,000);
- Preclinical testing of OPT-1 and formulation development of (in the approximate amount of \$1,900,000); and
- Preclinical testing of CFX-1 and formulation development (in the approximate amount of \$1,500,000).

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 MRX-6, CFX-1 and OPT-1;
- the results of preclinical studies of OPT-1 and CFX-1 and the timing of initiation, progress, results and costs of any clinical trials that we may initiate based on the preclinical 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 preclinical 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.

Our recent financings may result in significant dilution for existing stockholders.

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. 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 of clinical development 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 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 regulatory applications, have not received regulatory approval, nor distributed or sold any drugs. The success of our business depends substantially upon our ability to develop 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. Although the Phase 2 clinical trial for MRX-4 was conducted under ICH rules, which comply with the FDA's rules, the Phase 2 clinical trial for MRX-6 was conducted as an academic study and, thus, is neither ICH- nor FDA-compliant. We are therefore required to execute another clinical trial 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. We intend to execute such a trial in 2015. We currently expect to submit Investigational New Drug, or IND, applications MRX-6 (for dermatitis) in the second half of 2014 and potentially OPT-1 and CFX-1 in 2015. We also plan to initiate pre-clinical work to advance OPT-1 for ophthalmologic indications and potentially CFX-1 in cystic fibrosis in 2014. 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 preclinical studies or 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 preclinical 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 preclinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical 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 or delay the analysis of data derived from them. 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 protocols 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;
- preclinical or clinical trials may produce negative or inconclusive results, which may require us or any potential future collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- even if preclinical 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, the IRBs at the sites where the IRBs are overseeing a trial, or other regulatory authorities 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 is dependent on the season of the year;
- unforeseen safety issues; or
- the lack of adequate funding to continue the synthesis, 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 are 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;
- regulators or IRBs may not authorize us or any potential future collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or we may experience substantial delays in obtaining these authorizations;
- 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. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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 preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained from preclinical 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 are 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 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.

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 preclinical 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.

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D as established in 2003. However, the legislation also implements cost containment measures that could adversely affect our revenues. These measures include increased drug rebates under Medicaid for brand name prescription drugs, such as our prospective product candidates, and extension of these rebates to Medicaid managed care, each of which have reduced the amount of net reimbursement received for our prospective product candidates and would reduce the amount of net reimbursement for any other products that we and/or any potential future collaborators may develop and sell. The legislation also extended 340B discounted pricing on outpatient drugs to children's hospitals, critical access hospitals, and rural health centers, which has reduced the amount of reimbursement received for drugs purchased by these new 340B-covered entities. Additional provisions of the health care reform legislation may negatively affect our revenues and prospects for profitability in the future. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we are assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, made in the preceding year if such sales exceed a defined threshold. As part of the health care reform legislation's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), as of January 1, 2011, we are required to provide a 50% discount on brand name prescription drugs, including our prospective product candidates, sold to beneficiaries who fall within the donut hole. The health care reform legislation has been subject to judicial challenge. While some courts have upheld the law, other courts have concluded that the individual mandate component of the law is unconstitutional. One of those courts determined that the individual mandate component could not be severed from the law and therefore concluded that the entire law was void. All of the rulings on the merits are being appealed. There is no certainty regarding the final outcome of the litigation or the impact of the outcome on the pricing and potential profitability of any products that we and/or any potential future collaborators may develop.

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.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, together the Affordable Care Act or ACA. This law is expected to result in an increase in the number of people who are covered by both public and private insurance and is also expected to substantially change the way health care is financed by both government health program and private insurers, and significantly impact the pharmaceutical industry. The ACA contains a number of provisions that may impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the ACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of any products that we develop. In addition, as part of the ACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a 50% discount on any branded prescription drugs that we develop sold to beneficiaries who fall within the donut hole. While it is too early to predict all the specific effects the ACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

The availability of government reimbursement for prescription drugs is also likely to be impacted by the Budget Control Act of 2011, which was signed into law on August 2, 2011. This law is expected to result in federal spending cuts totaling between \$1.2 trillion and \$1.5 trillion over the next decade over half of which will include cuts in Medicare and other health related spending.

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 is 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, preclinical 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 geographics. 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 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 preclinical 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 14 United States and 12 foreign issued patents; and 16 United States and 44 foreign patent applications, as well as two pending international patent application. Issued patents which cover our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-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-4, MRX-5, MRX-6, OPT-1 and CFX-1 outside of the United States, will expire between 2021 and 2025, depending on the specific compositions. We have pending patent applications for formulations of our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-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. We have an issued patent directed to methods of manufacturing which covers our product candidates compounds in the United States and which will expire in 2021. Issued patents directed to methods of treatment using our product candidates MRX-4, MRX-5, MRX-6 and OPT-1 in the United States, will expire between 2021 and 2024, depending on the specific indication: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis (OPT-1) and inflammatory bowel disease (MRX-5). Issued patents directed to use of our product candidate: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), and inflammatory bowel disease (MRX-5) and CFX-1 for indications outside of the United States, will expire between 2021 and 2026, depending on the specific indication: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), inflammatory bowel disease (MRX-5), and cystic fibrosis (CFX-1). We have pending patent applications for use of our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-1 that, if issued: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), inflammatory bowel disease (MRX-5) and cystic fibrosis (CFX-1) 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: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), inflammatory bowel disease (MRX-5) and cystic fibrosis (CFX-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 Our Ordinary Shares and ADSs

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.

Because we became a reporting company under the Exchange Act by means of filing a Form 20-F, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering (“IPO”) of our Ordinary Shares or ADSs, we do not expect security analysts of major brokerage firms to provide coverage of our company in the near future. In addition, major investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we had become a public reporting company by means of an IPO. The failure to receive research coverage or support in the market for our Ordinary Shares or ADSs will have an adverse effect on our ability to develop a liquid market for our ADSs.

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;
- unanticipated problems in the supply of the raw materials used to produce our product candidates;
- the commercial success of any product approved by the FDA 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 stockholders;
- 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 March 12, 2014, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 11.1% of our outstanding Ordinary Shares (approximately 14.3% of our Ordinary Shares on a fully diluted basis). 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 are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, and any adverse results from such evaluation could result in a loss of investor confidence in our financial reports and have an adverse effect on the price of our ADSs.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish a report by our management on our internal control over financial reporting for fiscal 2013, which is the year following our first annual report required to be filed with the SEC. Such report contains, 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. This assessment 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 \$860,000 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 stockholder 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 electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of such election, our financial statements may not be comparable to the financial statements of other public companies. 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 significant expenses and devote substantial 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 our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of other public companies. 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 electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of such election, our financial statements may not be comparable to the financial statements of other public companies. We cannot predict if investors will find our Ordinary Shares less attractive because we will rely on these exemptions. 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.

We are a foreign private issuer and you will receive less information about us than you would from a domestic U.S. corporation.

As a “foreign private issuer,” we are exempt from rules under the Exchange Act that impose certain disclosure and procedural requirements in connection with proxy solicitations under Section 14 of the Exchange Act. Our directors, executive officers and principal shareholders also are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder with respect to their purchases and sales of our shares. In addition, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. We will likely no longer qualify as a “foreign private issuer” as of the June 30, 2014 measurement date and, accordingly, would become subject to the reporting requirements of U.S. companies under the Exchange Act beginning January 1, 2015. We are contemplating reorganizing our company pursuant to a court-approved scheme of arrangement under the laws of England and Wales so that a company named Celsus Therapeutics, Inc. will become the Delaware holding company and Celsus Therapeutics Plc will become a wholly-owned subsidiary of Celsus Therapeutics, Inc. If such scheme were to be approved by the court and our shareholders, our ordinary shareholders, including holders of ADSs, would become stockholders in Celsus Therapeutics, Inc., which would become the publicly traded entity. Although we are considering this option, we may decide that it is too costly and time consuming to pursue at this time.

If we are deemed or become a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2013 or in any prior or subsequent years, there may be negative tax consequences for U.S. taxpayers that are holders of our Ordinary Shares or our ADSs.

We will be treated as a 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 may be treated as a PFIC for U.S. federal income tax purposes for the current and future taxable years. If we are a PFIC in 2013, or any prior or subsequent years, and a U.S. shareholder 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 Ordinary Shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. shareholder’s holding period for the Ordinary Shares (or ADSs, as the case may be); (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. shareholders who hold our Ordinary Shares or ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. However, we do not commit to maintain calculations of earnings and profits according to U.S. tax principles, and in the absence of such calculations, shareholders may be unable to obtain a QEF election.

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 enforce suits against our company. We are a public limited company under the Companies Act of 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 realize in the United States upon 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 will 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 actions against us and our respective directors and officers under English law and in English courts in order to enforce any claims that they may have against us or our directors and officers. The enforceability of any 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 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. 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 4. INFORMATION ON THE COMPANY

In this report, “Celsus”, the “Company,” “we,” “us,” and “our” refer to Celsus Therapeutics PLC.

A. History and Development of the Company

Our 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.

B. Business Overview

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 recently changed our corporate name from Morria Biopharmaceuticals PLC to Celsus Therapeutics PLC. We believe that we have created a new class of synthetic drugs 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 the Federal Drug Administration, or FDA, 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 such as allergies.

Inflammatory diseases therefore manifest in a wide range of symptoms, affecting any organ in the body and have diverse causes. Inflammatory diseases encompass such diverse diseases as respiratory diseases (e.g. allergic rhinitis, asthma, and chronic obstructive pulmonary disease (COPD)), alpha-1-antitrypsin, bronchiectasis, cystic fibrosis), chronic gastrointestinal diseases (e.g. Crohn's disease and ulcerative colitis), skin inflammations (e.g. dermatitis, eczema, psoriasis and rosacea), cardiovascular diseases (e.g. restenosis, thrombosis and acute cardiovascular syndrome), diseases of the eye (e.g. dry eye, uveitis, and conjunctivitis), diseases such as arthritis and related diseases (e.g. osteo-arthritis and rheumatoid-arthritis), autoimmune disorder (e.g. Lupus, Wegeners, and dermatomyositis), and disease of the central nervous system (e.g. 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 for treating contact dermatitis (a common type of eczema). The Phase 2a clinical trial for MRX-6 was conducted as an academic study and, thus, is neither ICH- or FDA-compliant. A second, multi-center, vehicle controlled, double blind, dose ranging study of MRX-6 study was carried out in Israel. Results of the study were reported on May 8, 2013. These results demonstrated that MRX-6 was a safe and effective treatment for chronic hand eczema secondary to contact dermatitis, replicating the results we saw in our earlier Phase IIa trial. The data announced on May 8 were from a multi-center Phase II double blind, vehicle controlled study of MRX-6 for the treatment of patients with chronic hand eczema due to allergic contact dermatitis (ACD). The results showed a 56% improvement in symptoms (dryness, scaling, redness, pruritus and fissures) from baseline in the MRX-6 treated hand/forearm, compared to a 24% improvement for vehicle ("placebo") treated hand/forearm ($p < 0.0001$). Each patient acted as his or her own control. Clinically significant benefit, defined as a $\geq 50\%$ 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, with no adverse events. The benefit was similar regardless of patient baseline score, study center or symptom sub-score.

We may also 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); 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 arthritis and related diseases (osteoarthritis and rheumatoid-arthritis).

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 42-46 High Street, Esher, Surrey KT109QY, United Kingdom.

Our Business 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 manufacturing, 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 PLA2 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 PLA2, our product candidates remain on the cell surface and target the pathologic-associated secretory PLA2 isomers (sPLA2), but do not interfere with the homeostatic isomers found inside the cell (cytosolic, cPLA2).

Steroids and Currently Available Alternatives

Steroids are the most commonly prescribed medications for inflammatory diseases because of their high potency and unparalleled 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 that relate to the risk of systemic corticosteroid absorption and include adrenal suppression, bone fracture among the elderly, and reduced bone growth and height in children. Adverse local effects may include 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-body therapies).

Non-steroid synthetic drugs include the old generation of non-specific COX inhibitors, such as ibuprofen and aspirin (possibly the most commonly used drug in the world), 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 produce 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 its related drug 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 artificial 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 inflammatory bowel disease. These drugs have a number of disadvantages: the drug intake 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 which 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 dermatitis can be divided into two primary groups: topical steroids, which are the most common treatment for dermatitis, and topical calcineurin inhibitors (TCI) such as Elidel® and Protopic®.

In the case of Elidel, topical calcineurin inhibitors are the only commonly used category of topical anti-inflammatory drugs aimed specifically at treating the inflammatory aspect of the disease. The two drugs are identical in their mechanism of action and potency. The latter is 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 of treatment if patients are unresponsive to steroids but are prescribed in order to avoid the use of topical steroids for safety issues. In 2005, the FDA assigned both drugs to a “black box” warning stipulating risks of cancerogenicity. The sales of both drugs have declined significantly and its patent has expired. The Elidel franchise was sold to Meda in 2011 for \$420 million.

According to sales figures for dermatitis drugs for 2010 compiled by GlobalData, a leading market research company, the total dermatitis sales was approximately \$2.0 billion for 2010. According to forecasts of GlobalData, the market is expected to expand and reach approximately \$3.6 billion in 2018.

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
Steroids	Effective; affect a wide range of inflammatory mediators	<i>Group A — steroids</i> 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: <i>Nasal sprays:</i> 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 <i>Topical (skin) steroids:</i> Local: atrophy, skin fragility, striae, purpura (itching), telangiectasia acne, contact dermatitis, rosacea, delayed wound healing, scarring, infections (local) Systemic: cataracts, glaucoma
COX inhibitors	Low potency; primarily used mainly as mild painkillers	<i>Group B — non-steroid synthetic drugs</i> 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®, Zflo®, Accolate®	Liver toxicity (Zflo®), Risk of infections (particularly lung infections such as pneumonia and TB), risk of cancer (particularly Lymphoma)
Antibodies and recombinant receptors	Varies with patients.	<i>Non-steroid biological drugs</i> 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
Our Product Candidates	Currently in phase 2 clinical trials; studies indicate excellent safety and promising efficacy	<i>Our Product Candidates</i> 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 hydrolyze 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 Zflo. 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.

Professor Saul Yedgar at the Hebrew University has conducted over two decades of research in the field of lipid conjugates and his work has been widely accepted by his peers, as evidenced by the large body of peer-reviewed papers he has had published in leading scientific journals, such as Thorax, American Journal of Physiology and GLIA demonstrating the efficacy (pre-clinical and clinical) of lipid conjugates in multiple models. The key role of PLA2 in inflammatory diseases was elucidated by multiple groups as far back as the early 1980s and is universally accepted in the scientific community according to numerous textbooks on this subject, such as “Progress in Lipid Research,” by Makoto Murakami et al., and “Cardiovascular Drugs Therapy,” by J.E. Burke and E.A. Dennis. Since the mid-1980’s, the key role of PLA2 in inflammation has become increasingly better understood and in the late 1990’s a number of clinical programs were launched using various PLA2 inhibitors to target a number of inflammatory diseases. These programs failed either due to poor clinical efficacy and/or high toxicity. The failure of these programs has been invaluable to our understanding of how to design an effective PLA2 inhibitor drug.

Research and Development

Since our inception in 2005, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs activities, quality assurance activities and license fees.

Our research and development expenditures were approximately \$1,276,000, \$1,483,000 and \$841,000 in the years ended December 31, 2013, 2012 and 2011, 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 and clinical research activities. Our planned research and development for fiscal 2014 includes personnel expenses, synthesis, formulation, toxicity studies and manufacturing work of MRX-6 and its respective Phase II clinical trials. In January through September 2013, we received investments totaling approximately \$14.2 million enabling us to continue the synthesis and formulation of MRX-6 prepare for additional Phase II trials. Furthermore, In February 2014, we closed a public offering raising gross proceeds of approximately \$9,200,000. The additional capital raised enabled us to initiate the following additional research and development activities:

- Conduct the formulation, manufacturing and toxicity studies of MRX-6 (in the approximate amount of \$2,900,000); and
- Phase II clinical trial of MRX-6 for dermatitis (in the approximate amount of \$1,000,000); and
- Preclinical testing and formulation of OPT-1 (in the approximate amount of \$1,900,000)
- Preclinical testing and formulation of CFX-1 (in the approximate amount of \$1,500,000).

Provided that we are able to raise additional capital, we expect our development expenses for fiscal year 2013 to increase and to be primarily focused on the following:

- the continued clinical development of MRX6;
- the synthesis and formulation of MRX-6, CFX-1 and OPT-1;
- if and to the extent the FDA permits us to continue developing our drugs;
- the continued preclinical development of other potential product candidates; and
- using the platform to identify and develop new product candidates.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described in “Risk Factors” of this prospectus, we may not be able to successfully develop and commercialize any of our product candidates.

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a New Drug Application, or NDA, may be submitted to the FDA. In responding to a NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may not grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. Even if the FDA grants marketing approval, the FDA may impose restrictions, limitations and/or warnings in the label of an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed. In some cases, the FDA may give conditional approval of a NDA for a product candidate on the NDA sponsor’s agreement to conduct additional clinical trials to further assess the product’s safety and effectiveness after NDA approval. Any approval of a NDA by the FDA conditioned on completing additional clinical trials may require the sponsor to discontinue further marketing of the product if data from the clinical trial fails to demonstrate sufficient efficacy and safety in accordance with the agreed-upon protocol for the clinical trial.

The successful development and commercialization of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development and commercialization of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- our ability to progress product candidates into preclinical and clinical trials;
- the scope, rate of progress and cost of our clinical trials and other research and development activities, including additional development activities or studies that may be required by the FDA if we are permitted to continue developing MRX-6, OPT-1, CFX-1 or other indications, as well as our ongoing and any future clinical trials of MRX-6, OPT-1 and CFX-1;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- future clinical trials;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future collaborators may develop;
- the effect of competing technological and market developments; and the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims;
- the costs of synthesis and formulation; and
- lack of adequate funding to continue the synthesis, formulation, manufacture and/or clinical trials.

Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

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” (e.g. bronchitis, appendicitis, dermatitis) but many other do not (e.g. 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 the first indication being contact 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 topical calcineurin inhibitors (TCI) 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, purpura (itching), telangiectasia, acne, contact dermatitis, rosacea, delayed wound healing, scarring, infections (local).
- Systemic: cataracts, glaucoma.

Topical Calcineurin Inhibitors

Topical calcineurin inhibitors are the only commonly used category of topical anti-inflammatory drugs aimed specifically at treating the inflammatory aspect of the disease. The two drugs are identical in their mechanism of action and potency. The latter is 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 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 cancerogenicity. The sales of both drugs have declined significantly and its patent has expired. Its franchise was sold to Meda Pharmaceuticals Inc. in 2011 for \$420 million.

According to sales figures for dermatitis drugs for 2010 compiled by GlobalData, a leading market research company, the total dermatitis sales was approximately \$2.0 billion for 2010. According to forecasts of GlobalData, the market is expected to expand and reach approximately \$3.6 billion in 2018.

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 (conjunctivitis and dry eye), cystic fibrosis and other inflammatory indications.

Clinical advancement of our lead product candidates

We are currently conducting Phase IIb clinical trial for MRX-6, a topical cream for dermatitis in Israel and Argentina. We anticipate completing our Phase II clinical trials during 2014 and submitting an application for the FDA's Investigational New Drug, or IND, in 2014. If this application is approved, we intend to seek licensing arrangements with international pharmaceutical companies.

MRX-4

Phase 1 clinical trial. We conducted Phase 1 clinical trials on MRX-4 in Israel. The clinical trial in Israel was approved by the Israeli Ministry of Health and was conducted at Ichilov Hospital at the Tel Aviv Medical Center on 16 subjects. The primary and only objective of the trial was safety, and it was based on a double blind study with a placebo control group, and patients were treated once a day. A double blind clinical trial is a trial in which two alternative treatments are given to two groups of patients: one is treated with a drug and the other a negative control group, which receives placebo treatment. In this trial, both the investigators and the subjects were unaware of which subjects belonged to the control group and which to the trial group. Only after concluding the trial and analyzing the results does the affiliation to these groups become clear. This way, the effect of prejudices and biases, the placebo effect and physical effects (including subconscious ones) are reduced. Randomization into the control and trial groups is vital, and the key assigning each participant in the trial to one of the groups is kept by a third party until the conclusion of the trial.

The trial showed that MRX-4 was well tolerated and no drug-related adverse effects were noted. A second Phase 1 trial was combined with a Phase 2 trial that was conducted in South Africa at the UCT Lung Research Institute, the results of which are discussed below.

Phase 2a clinical trials. MRX-4 completed a Phase 1/2a clinical trial in South Africa in 2008. The study, including all of its stages, has been conducted according to the requirements of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, and Good Clinical Protocol, or GCP, by third parties. As of March 15, 2014, we have invested approximately \$2,096,000 for this part of the Phase 2 clinical trial.

Beginning in 1990, the FDA and corresponding regulatory agencies of the EU and Japan commenced discussions to develop harmonized standards for preclinical and clinical studies and the format and content of applications for new drug approvals through a process known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Data from multinational studies adhering to GCP are now generally acceptable to the FDA and regulators in Australia, Canada, the EU, Japan and Latin American countries and the World Health Organization, or the WHO. GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data are credible and accurate and that the rights, safety, and well-being of trial subjects are protected. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. GCP includes review and approval (or provision of a favorable opinion) by an independent ethics committee, or IEC, before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study. The FDA enforces these GCP guidelines through periodic onsite inspections of trial sponsors, principal investigators, CRO trial sites, laboratories, and any entity having to do with the completion of the study protocol and processing of data.

As ICH GCP is the international standard that is compatible with both the FDA and EMA, we believe that our Phase 2 trial for MRX-4 was conducted in accordance with rules that are FDA-compliant. The MRX-4 clinical trial was a non-IND foreign study performed in accordance with ICH GCP standards, including review and approval by an independent ethics committee and the obtaining of the informed consent from its subjects in compliance with the requirements in the FDA's regulations. Moreover, the FDA is able to validate the data from the study through onsite inspection of the clinical site, if necessary.

The hay fever drug development project was coordinated by Sciluent Inc. (based in Virginia), a clinical research organization, or CRO, that specializes in promoting the development of products, obtaining regulatory approvals and managing projects for pharmaceutical companies. The trial was conducted in South Africa and included 105 allergic rhinitis patients who were treated for six days (morning and evening). The primary objectives of the study were to examine safety and tolerability of the drug, with the secondary objectives of examining the clinical and biochemical efficacy of MRX-4 in treating the illness. The study was conducted in accordance with ICH standards. The principal investigators were Profs. Eric Bateman and Paul Potter, both of whom have a global reputation in allergic rhinitis and asthma. The results of the study were reported to the international scientific community by Prof. Bateman at the annual conference of the European Academy of Allergy and Clinical Immunology that was held in London in June 2010.

The study consisted of two parts: the first compared MRX-4 to a placebo and examined the safety, tolerability and efficacy of the drug. The other was a positive control group that compared Rhinocort® (a widely used intranasal steroid spray for the treatment of rhinitis and that has been marketed for about a decade) — to a placebo group. The primary objective was met and there were no side effects related to the use of MRX-4 (no treatment emergent adverse events). The patients in the MRX-4 group demonstrated the same safety profile as patients in the placebo group. In addition to this, the positive control group (Rhinocort®) demonstrated signs of significant, and common, steroid treatment related effects (nasal bleeding, headaches and local infections), illustrating the need for a safe alternative to steroid treatment. The safety checks included a pharmacokinetic analysis, which examines whether the drug that is administered as a nasal spray penetrates the blood system. The results of this test showed that there are no remnants of MRX-4 in the bloodstream, making it much safer than steroid-based drugs and Singulair®, both of which penetrate the bloodstream and thereby potentially affect other parts of the body. In addition, the group treated with MRX-4 demonstrated reductions in coughing, headaches and the need for bronchodilator rescue medication during the six days of treatment. This is potentially an important indication for the potency of the drug.

The secondary objectives of the trial were also achieved: a significant improvement was found to have occurred in the overall index of clinical symptoms (known as total symptom scores), which is based on four separate symptoms and is the standard method for examining the efficacy of allergic rhinitis drugs. The drug was particularly effective in significantly improving headaches ($p = 0.015$) and in improving nasal congestion (a “blocked nose”) ($p = 0.052$) (the p-value is the probability that the reported result was achieved purely by chance (e.g., a p-value £0.01 means that there is a 1% chance that the difference between the placebo group and the treatment group is purely due to chance). A p-value of 0.05 is a commonly used criterion for statistical significance). The need for bronchodilator rescue medication was also reduced pointing to the potential potency of MRX-4. Another secondary objective, which was met, was a significant decrease in biochemical mediators that constitute indications of an allergic reaction, and sometimes serve as an indication ($p < 0.05$) that is predictive of clinical efficacy. The indicators included, among others, changes in the white blood cell count and measurement of inflammatory mediators. Most of those mediators were suppressed by MRX-4 similarly to Rhinocort®.

No treatment emergent 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. We do not anticipate further clinical trials with MRX-4 for allergic rhinitis at this time.

MRX-6

Pre-clinical and Phase 1 clinical trials . From 2005 to 2007, we conducted pre-clinical development of the drug, which included trials in animal models. In 2007, we conducted an initial, exploratory size study (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 study was conducted under the supervision of Prof. Arieh Ingber, head of the Dermatology Department at Hadassah Ein-Kerem Hospital. The patients were treated for 28 days with MRX-6 (morning and evening) and double-blinded with placebo. The results showed significant clinical efficacy compared to the placebo group (69% improvement compared to 32% in the placebo group ($p = 0.0024$)), with efficacy being comparable to the common efficacy of steroid ointments. The efficacy is based on the standard medical index for assessing improvement in disease. Further, no drug-related adverse effects were identified. The results of this study were published in March 2007 in the International Journal of Inflammation and Immunopathology. From 2007 to early 2010, we further developed the chemical synthesis and formulation of MRX-6.

Phase 2 clinical trials

We received approval to conduct a Phase 2 clinical trial of MRX-6. We have completed first-in-patient clinical studies (Phase 2a) of the MRX-6, a topical cream for treating contact dermatitis (a common type of eczema). The Phase 2a clinical trial for MRX-6 is being conducted as an academic study and, thus, is neither ICH- or FDA-compliant. We are already underway in the Phase 2b clinical study for MRX-6 which is also an academic study. The MRX-6 study is currently underway in Israel. This trial is being conducted on 80 patients at Hadassah Ein-Kerem Hospital in Israel. Patients are treated for 21 days (morning and evening) with the same tests as we conducted in the previous study. The dermatitis drug development project is being coordinated by Target Health Inc., a New York based CRO. 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 not an ICH-compliant trial. The primary difference between academic studies and the ICH rules is that the academic studies do not require usage of independent monitors, which ICH studies do. While the FDA will not approve a drug based on academic studies, companies do routinely submit results of academic studies as supportive evidence. The FDA does consider such results as definitive, and the Company will be required to conduct an ICH-compliant clinical trial.

On May 8, 2013, we announced positive results from a multi-center Phase II double blind, vehicle controlled study of MRX-6 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 (dryness, scaling, redness, pruritus and fissures) from baseline in the MRX-6 treated hand/forearm, compared to a 24% improvement for vehicle (“placebo”) treated hand/forearm ($p < 0.0001$). Each patient acted as his or her own control. Clinically significant benefit, defined as a 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, with no adverse events. 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		MRX6	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

MRX-6 is formulated as a topical (local) treatment cream. Subject to the results of the trials, we intend to submit an IND application to the FDA for this drug during the second half of 2014 so that we may conduct clinical trials in the United States. As of March 15, 2014, we have invested approximately \$1,403,000 for this part of the Phase 2 clinical trial and expect to invest approximately \$5 million overall for the research and development of MRX-6.

Advancement of our additional research and development programs

We also plan to initiate a number of preclinical studies for the development of drugs for inflammatory eye diseases (OPT-1), cystic fibrosis (CFX-1), and other inflammatory diseases. We intend to conduct such studies throughout 2014; OPT-1 pre-clinical studies planned to take place during 2014 include synthesizing and formulating the drug, conducting safety studies and animal model optimization screening. Potential CFX-1 pre-clinical studies are intended to take place beginning in the second quarter of 2014, in which we intend to synthesize and formulate the drug, conduct safety studies and animal model optimization screening.

No treatment emergent 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-4, MRX-5, MRX-6, OPT-1 and CFX-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-4, MRX-5, MRX-6, OPT-1 and CFX-1 for treating patients having allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), inflammatory bowel disease (MRX-5), and/or cystic fibrosis (CFX-1).

We own or have exclusive rights to 14 United States and 12 foreign issued patents; and 16 United States and 44 foreign patent applications, as well as two pending international patent application. Issued patents which cover our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-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-4, MRX-5, MRX-6, OPT-1 and CFX-1 outside of the United States, will expire between 2021 and 2025, depending on the specific compositions. We have pending patent applications for formulations of our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-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. We have an issued patent directed to methods of manufacturing which covers our product candidates compounds in the United States and which will expire in 2021. Issued patents directed to methods of treatment using our product candidates MRX-4, MRX-5, MRX-6 and OPT-1 in the United States, will expire between 2021 and 2024, depending on the specific indication: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis (OPT-1) and inflammatory bowel disease (MRX-5). Issued patents directed to use of our product candidate: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), and inflammatory bowel disease (MRX-5) and CFX-1 for indications outside of the United States, will expire between 2021 and 2026, depending on the specific indication: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), inflammatory bowel disease (MRX-5), and cystic fibrosis (CFX-1). We have pending patent applications for use of our product candidates MRX-4, MRX-5, MRX-6, OPT-1 and CFX-1 that, if issued: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), inflammatory bowel disease (MRX-5) and cystic fibrosis (CFX-1) 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: allergic rhinitis (MRX-4), contact dermatitis (MRX-6), conjunctivitis and dry eye (OPT-1), inflammatory bowel disease (MRX-5) and cystic fibrosis (CFX-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 our principal shareholder, Prof. Yedgar, is conducting 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. Our breach of this license or failure to obtain a license to technology required to develop, test and commercialize our products may seriously harm our business.

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 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 is performed on an as-needed basis.

We have no direct experience in manufacturing any of our product candidates, and we currently lack the resources or capability to manufacture any of our product candidates on a clinical or commercial scale. As a result, we will be dependent on third parties for the manufacturing 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 Ziarc 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. Ziarc Pharma, Ltd. is pursuing development of cytosolic PLA2 inhibitors, a different segment of the PLA2 pathway, and Ziarc's drug candidates are entirely different in both structure (chemical class) and function to Celsus's product candidates. Other companies, such as Anacor Pharmaceuticals, 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.

Property, Plant and Equipment

We do not own any property or fixed assets in our London office. We 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 \$600, based on an exchange rate as of March 12, 2014) (excluding VAT) per month. Each party may terminate this arrangement by giving three months' advance notice.

Legal Proceedings

We are not involved in any material legal proceedings.

Employees

As of December 31, 2013, we had four full-time employees. As of December 31, 2012 and 2011, we had two full-time employees and one full-time employee, respectively. As of December 31, 2013 and March 12, 2014, two employees were engaged in research and development and two 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 preclinical 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 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.

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 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 preclinical trials we conduct on animals in Israel. In order to conduct preclinical trials 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 and South Africa 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 and the South African Medicines Control Council. 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 preclinical 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 and the Lung Research Institute in South Africa, where we have conducted our Phase 1 and 2 trials, as well as the Israeli Ministry of Health and the South African Medicines Control Council.

On May 5, 2008, the Department of Health of The Republic of South Africa approved the clinical trial application of MRX-4.

On July 14, 2009 the Hadassa Hospital, Jerusalem, notified us that the Helsinki Committee approved the clinical trial application of MRX-6 on January 2, 2009.

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 preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application 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;
- 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 approval 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. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application 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. Our submission of an IND, or those of our collaborators, may not result in FDA authorization to commence a clinical trial. 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, preclinical 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 or an additional pivotal Phase 3 clinical trial. 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 preclinical 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 and our collaborators 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, imposes new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and includes 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 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. For example, in March 2010, President Obama signed one of the most significant health care reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively referred to as the PPACA. The PPACA will significantly impact the pharmaceutical industry. The PPACA will require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the PPACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the PPACA on our business is unclear.

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.

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:

<u>Name</u>	<u>Position/Institutional Affiliation</u>
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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.

Name	Position/Institutional Affiliation
<p>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</p>	<p>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.</p> <p>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.</p>

Name

Position/Institutional Affiliation

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.

C. 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.

D. Property, Plant and Equipment

We do not own any property or fixed assets in our London office. We 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 \$600, based on an exchange rate as of March 12, 2014) (excluding VAT) per month. Each party may terminate this arrangement by giving three months' advance notice.

Item 4A. UNRESOLVED STAFF COMMENTS

None.

Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. Operating Results

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly those in "Item 3. Key Information —Risk Factors."

Overview

Celsus 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 created a new class of synthetic drugs 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.

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

Inflammatory diseases therefore manifest in a wide range of symptoms, affecting any organ in the body and have diverse causes. Inflammatory diseases encompass such diverse diseases as chronic gastrointestinal diseases (e.g. Crohn's disease and colitis), skin inflammations (e.g. dermatitis, eczema, psoriasis and rosacea), cardiovascular diseases (e.g. restenosis, thrombosis and acute cardiovascular syndrome), diseases of the eye (e.g. dry eye, uveitis, and conjunctivitis), disease of the central nervous system (e.g. multiple sclerosis) and even conditions affecting multiple organs (e.g. sepsis, lupus and scleroderma). However, while the causes and symptoms of these diseases are diverse, their treatment is often the same: anti-inflammatory drugs.

The technology for Celsus's product candidates is based on research conducted by Prof. Saul Yedgar, our principal shareholder, 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 in Phase II development is MRX-6, a topical cream for treating contact dermatitis (a common type of eczema). We are also undertaking 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), 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.

We have completed first-in-patient clinical studies (Phase 2) of our lead product candidate MRX-6, a topical cream for dermatitis, in Israel. We anticipate completing our Israel based Phase 2 MRX-6 clinical trials by the second half 2014 and submitting an application for the FDA's Investigational New Drug, or IND, program for MRX-6 by the second half of 2014. We potentially also plan to submit an IND for OPT-1 and CFX-1 in 2015. If these applications are approved, we intend to seek licensing arrangements with international pharmaceutical companies.

We have also initiated a number of preclinical studies for the development of drugs for inflammatory eye diseases (OPT-1), cystic fibrosis (CFX-1) and other inflammatory conditions. We intend to conduct such studies throughout 2014. OPT-1 pre-clinical studies planned to take place during 2014 include synthesizing and formulating the drug, conducting safety studies and animal model optimization screening. CFX-1 pre-clinical studies are intended to be initiated in the first half of 2014, in which we intend to synthesize and formulate the drug, conduct safety studies and animal model optimization screening. These studies will continue throughout 2014.

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 preclinical studies and clinical trials. We primarily use external service providers to manufacture our product candidates for clinical trials and for all of our preclinical 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, 2013, we had an accumulated deficit of \$20,542,000. 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.

Recent Developments

February 2014 Public Offering

On February 5, 2014, Celsus Therapeutics Plc (the “Company”) completed a public offering of 1,533,333 ADSs on the NASDAQ Capital Market at a price of \$6.00 per ADS (or \$0.60 per ordinary share), which included the full exercise by the underwriter of its option to purchase 200,000 additional ADSs. Each ADS represents ten of the Company’s ordinary shares. The proceeds from this offering, including from the exercise of the over-allotment option, before underwriting discounts and commissions and other offering expenses, were approximately \$9,200,000 (less approximately \$1,100,000 in issuance costs). In connection with the offering, Celsus’s ADSs were approved for listing on the NASDAQ Capital Market under the trading symbol “CLTX” and began trading there on January 31, 2014. In connection with its listing on the NASDAQ Capital Market, the ADSs ceased trading on the OTCQB on January 30, 2014.

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 electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Additionally, we are in the process of evaluating 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 ASC505, “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 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 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.

Since all of our financing transactions through October 2011 were in consideration for Ordinary Shares, the fair value of the Ordinary Shares underlying the valuation of the options, warrants and deferred shares through October 2011, had been determined by management, based on the Ordinary Share prices in the equity financing rounds at adjacent dates to each measurement date. In determining the Ordinary Shares' fair value, the Company considered the share prices in the financing rounds both before and after each measurement date. Our share issuances were as follows:

During March to August 2011, we issued, in several financing rounds, 522,026 Ordinary Shares of £0.01 par value each, in consideration for \$951,000, at prices of \$1.63 – \$1.95 per share. Therefore, in measuring the fair value of options, warrants and deferred shares during March to September 2011, we used an Ordinary Share price of \$1.63-\$1.95 per share in our underlying assumptions.

In measuring the fair value of options, warrants and deferred shares in December 2011, for the first time we used a valuation method to determine our Ordinary Share price. That is, because in January 2012, for the first time, we issued in a financing a unit that is composed of shares and warrants. Between January and September 2012, we issued to investors 260,875 Ordinary Shares, £0.01 par value each, at a price of \$2.00 per unit, for total gross proceeds of approximately \$522,000. The investors were also issued warrants to purchase 280,106 Ordinary Shares, at an exercise price of \$2.00. 39,500 of such warrants granted in January 2012 at an exercise price of \$1.00 were modified in April 2012, to a total of 79,000 at an exercise price of \$2.00 per share. We accounted for these changes as modifications in accordance with ASC 718. We calculated the incremental value of these modifications and recorded a deemed dividend to additional paid-in capital. In June 2012, we issued 10,000 of Ordinary Shares, £0.01 par value each, at a price of \$2.25 per share, for total gross proceeds of approximately \$23,000. This financing round was furnished with 50% warrant coverage, to purchase 5,000 Ordinary Shares, at an exercise price of \$2.25 per share. In August 2012, we issued 232,558 Ordinary Shares, £ 0.01 par value each, at a price of \$1.72 per share, for total gross proceeds of approximately \$400,000. The investor also received warrants to purchase 232,558 Ordinary Shares, at an exercise price of \$1.72 per share.

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.

Consequently, in determining the Ordinary Share value we applied the market approach taking into account our actual equity transactions. As of December 31, 2013, the value was \$0.57 and ranged between \$0.57 – \$1.73 in 2013. In 2012, the value ranged from \$1.54 – \$1.72 and was \$1.58 as of December 31, 2011. 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. Subsequent financings in September 2013 and February 2014 did not include any warrant coverage.

In determining the valuations of our Ordinary Shares prior to being a public trading 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.

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.

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.

Results of Operations

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.

For the years ended December 31, 2012 and December 31, 2011

Research and development expenses

Research and development expenses for the year ended December 31, 2012 were approximately \$1,483,000 compared to \$841,000 for the year ended December 31, 2011. This 76% or \$642,000 increase was due to higher expenses of approximately \$476,000 for formulation and synthesis activities, manufacturing and clinical trials, \$144,000 for salary expenses, \$25,000 for indirect expenses, offset by \$3,000 higher stock-based compensation expenses in 2011.

Provided that we are able to raise additional capital, we expect our research and development expenses will fluctuate over the next several years as we conduct additional clinical trials to support the clinical development of MRX-4 and 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, 2012 were approximately \$2,184,000 compared to \$1,406,000 for the year ended December 31, 2011. This 55% or \$778,000 increase was primarily due to higher expenses of approximately \$329,000 of stock-based compensation expense related to warrants granted to employees, board members and consultants, \$301,000 for consulting, professional and accounting fees, \$130,000 for legal fees and \$120,000 for salaries, offset by lower expenses of \$36,000 for board fees and \$66,000 of other miscellaneous expenses.

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

Financial income/expenses

Financial expenses for the year ended December 31, 2012 was approximately \$601,000 compared to financial income of \$128,000 for the year ended December 31, 2011. This change was primarily attributed to \$898,000 of interest expense, \$137,000 of issuance costs related to the April 2012 Financing, offset by \$418,000 for the revaluation of the deferred shares and warrant liabilities and British Pound and US Dollar exchange rate differences and bank fees of \$16,000 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 \$5,450,000 during the year ended December 31, 2013 compared to \$2,134,000 used by operating activities during the year ended December 31, 2012. The 155% increase in cash flow used in operating activities of approximately \$3,316,000 can be primarily attributed to reducing our accrued payables after completion of our financing in September and the initiation of additional formulation and manufacturing activities in the fourth quarter.

In both 2013 and 2012, we had no investment activity and anticipate our investment will be minimal in the future.

Net cash provided by financing activities was approximately \$12,003,000 during the year ended December 31, 2013, compared to approximately \$3,232,000 during the year ended December 31, 2012. Financing activities in fiscal 2013 and 2012 were comprised of cash proceeds from the issuance of shares, warrants and convertible notes offset by the repayment of the convertible notes in 2013.

As of December 31, 2013, we had approximately \$7,657,000 in cash and cash equivalents, an increase of approximately \$6,553,000 from December 31, 2012. In addition, as of December 31, 2013, we had accumulated losses in the total amount of approximately 20,542,000 and had cumulative negative cash flow from operating activity in the amount of approximately \$16,197,000.

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 March 12, 2014, we have existing cash and investment securities of approximately \$14.0 million.

We are constantly attempting to address 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 stockholders may experience significant dilution. If we are unable to raise funds when required or on acceptable terms, we may have to curtail, or possibly cease operations. We believe that our existing cash and investment securities will be sufficient to support our current contemplated operating plan through June 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 MRX-6, CFX-1 and OPT-1; the results of preclinical studies of OPT-1 and CFX-1 and the timing of initiation, progress, results and costs of any clinical trials that we may initiate based on the preclinical 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 preclinical 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, etc.

Our research and development expenditures were \$1,276,000, \$1,483,000 and \$841,000 in the years ended December 31, 2013, 2012 and 2011, 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, preclinical and clinical research activities.

We incurred the following research and development expenses in the years ended 2013, 2012 and 2011:

	2013	2012	2011
Direct Expenses:			
MRX-4	\$ 428	\$ 801	\$ 94
MRX-6	245	229	564
Other	161	70	—
Total operating expenses	<u>834</u>	<u>1,100</u>	<u>658</u>
Indirect Expenses:			
Staffing	419	361	182
Other indirect	23	22	1
	<u>442</u>	<u>383</u>	<u>183</u>
Total Research and Development	<u>\$ 1,276</u>	<u>\$ 1,483</u>	<u>\$ 841</u>

Trend Information

For a discussion of Trend information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operation — Overview and — Results of Operations.”

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, 2013.

Contractual obligations	Total	Payments due by period			
		Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Lease of office space	\$ 1,500	\$ 1,500			
Research and development – Yissum	\$ 140,000	\$ 70,000	\$ 70,000		
Total	\$ 141,500	\$ 71,500	\$ 70,000		

We have minimum rental commitments of approximately \$600 plus VAT for each month. The lease shall continue until it is terminated with three months prior written notice. Our contingent liability as of December 31, 2013 was approximately \$1,800 to be paid during 2014.

The license agreement between 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. The additional services fees shall be payable in semi-annual payments.

Quantitative and Qualitative Disclosures About Risk

Risk Management Framework

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

Currency Exchange Rate Sensitivity

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

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

Interest Rate Sensitivity

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

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 have elected to opt out of all other provisions of the JOBS Act, including the provision that allows us to take advantage of an extended transition period to comply with new or revised accounting standards until such time as private companies would be required to comply. This latter decision to opt out of the extended transition period to comply with new or revised accounting standards under the JOBS Act is irrevocable.

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 this 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 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

Directors

Our Articles of Association, as amended, provide that our business is to be managed by or under the direction of the board of directors. Our board of directors is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our board of directors currently consists of eight members, classified into three classes. 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.

<u>Name</u>	<u>Director Class and Position</u>
Mark S. Cohen	Class C Director — Executive Chairman of the Board; Nominating and Corporate Governance Committee.
David Sidransky, M.D.	Class C Director — Compensation Committee (Chairman); Nominating and Corporate Governance Committee
Dr. Johnson Yiu-Nam Lau, M.B., B.S., M.D., F.R.C.P.	Class B Director — Audit Committee
Prof. Saul Yedgar, Ph.D.	Class A Director
Amos Eiran	Class B Director — Audit Committee;
Fredric Price	Class A Director — Compensation Committee; Nominating and Corporate Governance Committee (Chairman)
Robert F. Doman	Class A Director — Compensation 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 46, 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, 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, New Jersey and Israel, and he is a registered patent attorney in the United States.

David Sidransky, M.D., age 53, has served as a director of our board of directors since June 13, 2007. Currently, Mr. 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 Lilly. He also serves as a member of the board of directors of K-V Pharmaceutical Company (NYSE: KV-A), Tamir Biotechnology, Inc. (ACLE.PK), 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 53, 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 also serves 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.

Saul Yedgar, Ph.D., age 72, has served as a member of our board of directors since January 28, 2005. He had been our Chief Scientific Officer from 2005 until December 8, 2013. Since June 2010, he has been a Prof. Emeritus of the Hebrew University of Jerusalem School of Medicine, where he served as a Prof. of Biochemistry since 1982. Prof. Yedgar carried out work at the NIH, Bethesda, MD; Institute Curie, Paris; and Aachen University of Applied Sciences, Germany. He is a member of various international scientific committees and editorial boards, including the European the International Biorheology Society, and the Journal Biorheology for Biorheology and Microcirculation Society, and has received the following international awards: The Hebrew University — Hadassah Medical School Prize for Outstanding Ph.D. research; The Hadassah University — Hospital Postdoctoral award; CNRS (Centre National Recherche Scientific) fellowship for research in Institut Curie, France; The US Cystic Fibrosis Foundation award for new ideas in Cystic Fibrosis research; The Henri de Rothschild award for research in Institut Curie, Paris, France; The Walter & Greta Stiel Chair in Heart Studies (Hebrew University); and the Kaye Innovation Prize for inventing and development of the platform of the Multi-Functional Anti-Inflammatory drugs (licensed to us). Prof. Yedgar has authored over 120 scientific papers. Prof. Yedgar received his B.S. from the Bar-Ilan University Dept. of Chemistry, his M.S. from The Hebrew University, Dept. of Physical Chemistry and his Ph.D. from The Hebrew University — Hadassah Medical School, Jerusalem in 1977. Prof. Yedgar also conducted post-doctoral studies at the University of California, San Diego, Department of Medicine, after which he received his position in 1982 at the Department of Biochemistry at the Hebrew University Faculty of Medicine in Jerusalem.

Amos Eiran, age 77, 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 of Bank HaPoalim and from August 1993 to August 1997, served as director 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.

Fredric Price, age 68, has served as a member of our board since June 20, 2013. Mr. Price is Executive Chairman of the Board of Directors of Chiasma, having served as its Chairman and CEO from 2008 to 2013, stepping down as CEO a month ago after completing a strategic collaboration for its Phase 3 oral drug candidate in acromegaly with Roche. Previously, he was Executive Chairman of the Board of Directors of Omrix Biopharmaceuticals (2004 – 2008) a member of the Board of Directors of Enobia Pharma (2006 – 2012), a member of the Board of Directors of Pharmasset (2007 – 2010), Executive Chairman of the Board of Directors of Peptimmune (2007 – 2011), Chairman of the Board of Directors and CEO of BioMarin Pharmaceutical (2000 – 2004) and CEO and a member of the Board of Directors of Applied Microbiology (1994 – 2000). Mr. Price is also currently serving as Chairman of the Board of BioBlast and a member of the Advisory Board of FDNA. His earlier experience includes having been Vice President of Finance and Administration and CFO of Regeneron Pharmaceuticals (1991 – 1994), the founder of the strategy consulting firm RxFDP (1986 – 1991), and Vice President of Pfizer Pharmaceuticals with both line and staff responsibilities (1973 – 1986). He received a BA from Dartmouth College and an MBA from the Wharton School of the University of Pennsylvania.

Robert F. Doman, age 64, 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. Bob currently serves as a member of the Board of Directors of Echo Therapeutics, Inc. (NASDAQ: ECTE). 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 Sero 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
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 45, 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 46, 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 49, 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.

B. Compensation

For the fiscal year ended December 31, 2013, the aggregate cash compensation that we paid to our directors and executive officers set forth below was \$829,905. We do not have a requirement to, and have not, set aside pension or retirement benefits for our officers or directors.

The following table provides information on all of the compensation paid, or due to be paid, by our company to each of our current directors and executive officers for the years ended December 31, 2012 and 2013, respectively:

Name	Cash
Mark S. Cohen	
2012	\$ 4,051(1)
2013	\$ 17,500(1)
Dr. Johnson Yiu Nam Lau, M.B., B.S., M.D., F.R.C.P.	
2012	\$ 2,498(2)
2013	\$ 12,500(2)
David Sidransky, M.D.	
2012	\$ 4,051(3)
2013	\$ 17,500(3)
Amos Eiran	
2012	\$ 0
2013	\$ 12,500(4)
Fredric Price	
2012	\$ 0
2013	\$ 17,500(5)
Robert Doman	
2012	\$ 0
2013	\$ 12,500(6)
Allan Shaw	
2012	\$ 0
2013	\$ 17,500(7)
Prof. Saul Yedgar, Ph.D.	
2012	\$ 4,051(8)
2013	\$ 66,000(9)
Dov Elefant	
2012	\$ 145,968(10)
2013	\$ 213,472(10)
Gur Roshwalb, MD ⁽¹¹⁾	
2012	\$ 0
2013	\$ 402,933
Pablo Jimenez, MD ⁽¹²⁾	
2012	\$ 0
2013	\$ 40,000

- (1) Consists of board of directors fees.
- (2) Consists of board of directors fees.
- (3) Consists of board of directors fees.
- (4) Consists of board of directors fees.
- (5) Consists of board of directors fees. Mr. Price joined our board in 2013.
- (6) Consists of board of directors fees. Mr. Doman joined our board in 2013.
- (7) Consists of board of directors fees. Mr. Shaw joined our board in 2013.
- (8) Consists of board of directors fees.
- (9) Consulting fees pursuant to Dr. Yedgar's May 2011 consulting agreement with us.
- (10) From January 2012 until September 23, 2013, Mr. Elefant had been earning a salary in the amount of \$12,500 per month and beginning September 24, 2013, Mr. Elefant has been earning a salary in the amount of \$16,667 per month. Includes \$50,000 bonus for 2013.
- (11) Dr. Roshwalb joined our company on March 4, 2013 and has been earning a salary in the amount of \$29,167 per month and was not employed by us during 2012. Includes \$115,500 bonus for 2013.
- (12) Dr. Jimenez was appointed as our Chief Medical Officer on October 23, 2013 and has been earning a salary in the amount of \$20,000 per month.

Employee Stock Option Plan

On August 28, 2007, our Board of Directors approved the 2007 Stock Option Plan, or the ESOP, amended on April 26, 2012, June 20, 2012 and April 29, 2013. Our shareholders approved the ESOP on June 20, 2013. The purpose of the ESOP 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 ESOP) to further the growth, development and financial success of our company by providing them with opportunities to purchase our shares pursuant to the ESOP and to promote the success of our business. The material terms of the ESOP 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 ESOP Plan shall not exceed 3,865,000 Ordinary Shares. Our board of directors may, at any time during the term of the ESOP Plan, increase the number of shares available for grant under the ESOP Plan. Options may be granted at any time. As of January 6, 2014, options to purchase 2,256,690 of our Ordinary Shares were outstanding. 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 ESOP Plan.

Options are exercisable pursuant to the terms under which they were awarded and subject to the terms and conditions of the ESOP 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 ESOP 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.

The table below sets forth the material terms of the outstanding options that were granted by us to our directors and executive officers as of December 31, 2013:

Optionee	Date of Grant	No. of Options		Exercise Price	Vesting Date	Expiration
		Granted				
Johnson Lau	August 28, 2007	68,250	\$	1.33 ⁽¹⁾	Fully vested	August 28, 2017
	April 26, 2012	30,000	\$	1.56	Fully vested	June 20, 2022
	April 26, 2012	25,000	\$	1.56	Fully vested	March 19, 2022
	September 24, 2013	70,000	\$	2.00	April 29, 2016	April 29, 2023
Mark Cohen	August 28, 2007	136,500	\$	1.33 ⁽¹⁾	Fully vested	August 28, 2017
	April 26, 2012	60,000	\$	1.56	Fully vested	June 20, 2022
	April 26, 2012	75,000	\$	1.56	Fully vested	March 19, 2022
	September 24, 2013	100,000	\$	2.00	April 29, 2016	April 29, 2023
David Sidransky	August 28, 2007	68,250	\$	1.33 ⁽¹⁾	Fully vested	August 28, 2017
	February 5, 2008	60,227	\$	1.31 ⁽²⁾	Fully vested	February 5, 2018
	April 26, 2012	30,000	\$	1.56	Fully vested	June 20, 2022
	April 26, 2012	25,000	\$	1.56	Fully vested	March 19, 2022
Amos Eiran	September 24, 2013	100,000	\$	2.00	April 29, 2016	April 29, 2023
	June 28, 2012	15,000	\$	2.00	Fully vested	June 28, 2022
Fredric Price	September 24, 2013	70,000	\$	2.00	April 29, 2016	April 29, 2023
	September 24, 2013	100,000	\$	2.00	April 29, 2016	April 29, 2023
Robert Doman	September 24, 2013	70,000	\$	2.00	April 29, 2016	April 29, 2023
Allan Shaw	October 2, 2013	100,000	\$	2.00	October 2, 2016	October 2, 2023
	October 2, 2013	100,000	\$	2.00	October 2, 2016	October 2, 2023
Dov Elefant	April 26, 2012	40,000	\$	1.56	Fully vested	January 11, 2022
	September 24, 2013	100,000	\$	2.00	July 1, 2014	July 1, 2023
Gur Roswalb	September 24, 2013	660,000	\$	2.00	September 24, 2017	September 24, 2023
Pablo Jimenez	November 1, 2013	130,000	\$	0.57	November 1, 2017	November 1, 2023
	November 1, 2013	70,000	\$	0.57	May 1, 2015 ⁽²⁾	November 1, 2023

(1) Exercise price of £0.80 converted using exchange rate of January 2, 2014

(2) Exercise price of £0.79 converted using exchange rate of January 2, 2014

Other Director Compensation

On February 18, 2005, we entered into an agreement with Mr. Mark Cohen pursuant to which he agreed to act as Chairman of our board of directors. Under the terms of that agreement, he is entitled to a fee of £1,000 for each meeting he attends. On February 13, 2011, Mr. Cohen confirmed that since 2005 he had agreed to waive all accrued fees owed to him under that agreement.

On February 21, 2005, we entered into an agreement with Professor Yedgar pursuant to which he agreed to act as a director for an initial term of 24 months. Under that agreement, Professor Yedgar was entitled, with effect from January 1, 2005, until the date on which we completed an offering raising up to £1,900,000, to be paid £1,000 for each board meeting he attended, subject to completion of such an offering, plus reimbursement of expenses reasonably incurred by him. On March 14, 2007, we entered into an agreement with Prof. Yedgar for his reappointment as a member of our board of directors. Under that agreement, Prof. Yedgar is entitled to £500 for every meeting he attends. To date, no amounts have been paid to Prof. Yedgar under this agreement and, on February 22, 2011, Prof. Yedgar agreed to waive all accrued fees owed to him as of such date.

On August 28, 2007, we entered into an agreement with Dr. Lau pursuant to which he agreed to serve as a director. Under the terms of that agreement, he is entitled to a fee of £750 for each meeting he attends. On February 2, 2011, Dr. Lau agreed to waive all accrued fees owed to him under that agreement.

On August 28, 2007, we entered into an agreement with Dr. Sidransky pursuant to which he agreed to serve as a director. Under the terms of that agreement, he is entitled to a fee of £750 for each meeting he attends. On February 2, 2011, Dr. Sidransky agreed to waive all accrued fees owed to him under that agreement.

On March 19, 2012, annual cash compensation for the non-employee directors was established at \$10,000 per year for four board meetings per year (or \$2,500 per meeting) as well as \$4,000 per year for the Chairman of each committee; commencing on the first day of the month after the Company completes a Permitted Private Placement as defined in the Purchase Agreement.

On April 29, 2013, annual cash compensation for the non-employee directors (excluding Prof. Yedgar and Dr. Cohen) was established at \$25,000 per year, \$10,000 per year for the Chairman of each committee and \$10,000 per year for the Executive Chairman; commencing on the completion of September 2013 private placement. On September 24, 2013, we granted 100,000 options each to Mark Cohen, David Sidransky and Fredric Price and 70,000 options each to Johnson Lau, Amos Eiran and Robert Doman. On October 2, 2013, we granted 100,000 options to Allan Shaw.

We have agreed to indemnify our directors and executive officers to the extent permitted by our director and officer liability insurance and English law.

We do not have, and have not had in the past, any profit-sharing plans, nor have we set aside or accrued any amounts to provide pension, retirement or similar benefits.

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 is 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's 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.

Prof. Saul Yedgar. On February 21, 2005, we entered into a consulting agreement with Prof. Yedgar, pursuant to which Prof. Yedgar agreed to render services to us in the field of compound research and development, clinical trials design and other projects as specified by us from time to time in accordance with the board of directors' requirements. This consulting agreement was terminable by either party upon 90 days' prior notice. The agreement included a non-competition provision that prohibited Prof. Yedgar, for a period of six months after the termination of such 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.

The agreement states that no employer-employee relationship shall exist between the parties, and if a competent court rules that such employer-employee relationship exists, Prof. Yedgar agrees to indemnify the Company for up to 45% of the consideration paid to him under the consulting agreement. In consideration for his services, Prof. Yedgar is entitled to a fee of £750 for each working day, up to a maximum of five working days per month (any additional days is subject to our prior approval) and no more than an aggregate of £12,000 in fees per annum.

On February 21, 2005, we entered into an agreement with Professor Yedgar pursuant to which he agreed to act as a director of the Company for an initial term of 24 months. Under that agreement, Professor Yedgar was entitled, with effect from January 1, 2005, until the date on which the Company completed an offering raising up to £1,900,000, to be paid £1,000 for each board meeting he attended, subject to completion of such an offering, plus reimbursement of expenses reasonably incurred by him. The agreement also included standard confidentiality provisions and provisions on non-solicitation of customers and employees of the Company for a period of two years after the termination of his services under that agreement.

On March 14, 2007, we entered into an agreement with Prof. Yedgar for his reappointment as a member of our board of directors. Under that agreement, Prof. Yedgar is entitled to £500 for every meeting he attends. The agreement includes a customary non-compete provision for a period of six months after his resignation or departure from the Company. To date, no amounts have been paid to Prof. Yedgar under this agreement and, on February 22, 2011, Prof. Yedgar agreed to waive all accrued fees owed to him as of such date.

Effective as of May 25, 2011, the consulting agreement described above was terminated and we entered into an employment agreement with Prof. Yedgar, which is governed by English law, pursuant to which he agreed to serve as our Chief Scientific Officer for a period of 60 months. This agreement may be terminated by: (a) either party, upon 30 days' prior notice, or (b) immediately by the Company, under certain circumstances, including material, recurring, continuing or a fundamental breach of his obligations under the agreement and his criminal conviction under certain circumstances. Prof. Yedgar is entitled to a monthly salary of NIS 8,312, or approximately an annual salary of £17,000, plus reimbursement of reasonable out-of-pocket expenses incurred by him in performing his duties once the Company completes its private placement. Our board of directors is authorized to review Prof. Yedgar's salary on annual basis, although it is not obligated to increase it. Prof. Yedgar is also entitled to 20 vacation days per year.

The employment agreement also includes a non-competition covenant that prohibits Prof. Yedgar, for a period of six months after the termination of his employment with us, to be involved in or provide technical, commercial or professional services to any business that competes, or is likely to compete, with our business in the United Kingdom, Israel or the United States. Prof. Yedgar is also obligated to keep confidential the confidential information of our Company.

The employment agreement also requires the approval of our board of directors in connection with the following actions: (a) incurring any capital expenditure in excess of any sum authorized by the board; and (b) obligate the Company, without prior written authorization from the Chief Executive Officer.

Dr. Yedgar resigned as our Chief Scientific Officer on December 8, 2013 and is no longer an executive officer of our company.

C. Board Practices

Board Practices

Our Articles of Association, as amended, provide that our business is to be managed by or under the direction of the board of directors. Our board of directors is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our board of directors currently consists of eight members, classified into three classes as follows: (1) Robert F. Doman, Fredric Price, Allan Shaw and Saul Yedgar constitute Class A, with a term ending at the 2014 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 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:

<u>Name</u>	<u>Commencement of Term</u>	<u>Expiration of Office</u>
Mark S. Cohen	December 21, 2004	2016 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
Prof. Saul Yedgar Ph.D.	January 28, 2005	2014 annual general meeting
Amos Eiran	June 28, 2012	2015 annual general meeting
Fredric Price	June 20, 2013	2014 annual general meeting
Robert F. Doman	June 20, 2013	2014 annual general meeting
Allan Shaw	October 2, 2013	2014 annual general meeting

Committees of the Board of Directors

Subject to certain exceptions, the rules of Nasdaq permit a foreign private issuer to follow its home country practice in lieu of listing requirements of Nasdaq. The Committees of our Board of Directors consist of an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

Audit Committee

Our Audit Committee currently consists of three members, appointed by the board of directors: 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.

Compensation Committee

Our Compensation Committee currently consists of three members, appointed by the board of directors: Dr. David Sidransky, Mr. Fredric Price and Robert F. Doman 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: Mark Cohen, Dr. David Sidransky and Mr. Fredric Price. Messrs. Sidransky and Price are independent within the meaning of SEC corporate governance rules of independence for purposes of the Nominating and Corporate Governance Committee. Mr. Price 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.

D. Employees

As of December 31, 2013, we had four full-time employees. As of December 31, 2012 and 2011, we had two full-time employees and one full-time employee, respectively. As of December 31, 2013 and March 12, 2014, two employees were engaged in research and development and two 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.

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 20, 2014 of each of our directors and executive officers individually and as a group.

Beneficial ownership generally includes voting or investment power over securities. Percentage of beneficial ownership is based on 55,561,283 of our Ordinary Shares outstanding as of March 20, 2014. Of this amount, approximately 6,533,705, or approximately 11.8%, of our outstanding Ordinary Shares are held by approximately 374 record holders in the United Kingdom.

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 Kingdom W1K 5JH.

	Number of Ordinary Shares Beneficially Owned ⁽¹⁾	Percentage of Ordinary Shares Beneficially
Directors and Executive Officers		
Mark S. Cohen	1,996,207 ⁽²⁾	3.2%
Dr. Johnson Yiu Nam Lau, M.B.,B.S., M.D., F.R.C.P.	123,250 ⁽³⁾	*
David Sidransky, M.D.	250,709 ⁽⁴⁾	*
Prof. Saul Yedgar, Ph.D.	3,793,375 ⁽⁵⁾	6.1%
Amos Eiran	15,000 ⁽⁶⁾	*
Dov Elefant	40,000 ⁽⁷⁾	*
Gur Roshwalb, M.D.	175,438 ⁽⁸⁾	*
Pablo Jimenez, M.D.	0	*
Fredric Price	258,768 ⁽⁹⁾	*
Robert F. Doman	0	*
Allan Shaw	33,530 ⁽¹⁰⁾	*
All directors and officers as a group (11 persons)	6,686,277	11.1%

* 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 March 20, 2014. 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.
- (2) Includes options to purchase, 136,500 Ordinary Shares at an exercise price of £0.80 per share (or \$1.56) 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, warrants to purchase 182,450 Ordinary Shares at an exercise price of \$2.00 per share and two call options to purchase from Prof. Yedgar (i) up to 50,700 Ordinary Shares at a purchase price of \$0.016 per share, and (ii) up to 152,000 Ordinary Shares at £0.01 per share, as amended on March 1, 2011, which expire on January 18, 2015 and March 12, 2017, respectively. This figure does not take into account a warrant issued to Pearl Cohen Zedek Latzer 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, LLP, 1500 Broadway, 12th 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 \$1.61), 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 and 25,000 Ordinary Shares at an exercise price of \$1.56 per share, which expire on March 19, 2022. Dr. Johnson's business address is c/o Kinex Pharmaceuticals, 701 Ellicott Street, Buffalo, New York 14203.
- (4) Includes options to purchase 183,477 Ordinary Shares as follows: 128,477 Ordinary Shares at an exercise price of £0.80 per share (or between \$1.56 and \$1.61), 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 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 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.
- (6) Includes options to purchase 15,000 Ordinary Shares at an exercise price of \$2.00 which expire on June 28, 2022. Mr. Eiran's business address is 2 Avner Street, Herzlia, Israel 4670402.

- (7) Includes options to purchase 40,000 Ordinary Shares at an exercise price of \$1.56 which expire on January 11, 2022.
- (8) Dr. Roshwalb was hired as Chief Executive Officer on March 5, 2013.
- (9) Mr. Price was appointed to the Board of Directors on June 20, 2013.
- (10) Mr. Shaw was appointed to the Board of Directors on October 2, 2013.

Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of March 20, 2014, by each person who we know beneficially owns 5.0% or more of the outstanding ordinary shares. Each of our shareholders has identical voting rights with respect to its shares. All of the information with respect to beneficial ownership of the ordinary shares is given to the best of our knowledge.

The beneficial ownership of ordinary shares is based on the 55,561,283 ordinary shares outstanding as of March 20, 2014 and is determined in accordance with the rules of the SEC and generally includes any ordinary shares over which a person exercises sole or shared voting or investment power. Of this amount, approximately 6,533,705, or approximately 11.8%, of our outstanding ordinary shares are held by approximately 374 record holders in the United Kingdom. For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of March 20, 2014 to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such ordinary shares. Our principal shareholders do not have different or special voting rights. All of the information with respect to beneficial ownership of the ordinary shares set forth below by shareholders that are not a member of our board of directors is based on information provided by such shareholders and/or in Schedule 13G filings with the SEC.

5% or More Shareholders

Baker Bros. Advisors LP and affiliates	5,263,162 ⁽¹⁾	9.5%
Franklin Advisors, Inc.	7,017,544 ⁽²⁾	12.6%
Sabby Management, LLC	6,314,410 ⁽³⁾	11.4%
Broadfin Capital	3,508,772 ⁽⁴⁾	6.3%
Prof. Saul Yedgar, Ph.D.	3,793,375 ⁽⁵⁾	6.1%

- (1) The number of shares beneficially owned before the offering 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 affiliates and its affiliates is 667 Madison Avenue, 21 st Floor, New York, NY 10065.

- (2) 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.
- (3) 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.
- (4) 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.
- (5) 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.

B. 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, 2010, certain related party transactions involving us.

The law firm of Pearl Cohen Zedek Latzer 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 ending December 31, 2013, 2012, 2011 and 2010, we received invoices from PCZL for services rendered and expenses incurred for approximately \$555,000, \$365,000, \$413,000 and \$262,000, respectively. As of March 12, there were no outstanding amounts due to PCZL. 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.

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 and beneficial owner of approximately 3.2% of our outstanding Ordinary Shares, 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 9, 2013, we sold an aggregate of 12,500 Ordinary Shares to Saul Yedgar, a beneficial owner of approximately 6.1% of our outstanding Ordinary Shares at a price of \$ 2.00 per share, for total gross proceeds of \$25,000. In connection with such purchase, Dr. Yedgar also received warrants to purchase an aggregate of 6,250 Ordinary Shares, at an exercise price of \$ 2.00 per share. On September 24, 2013, in connection with the most favored nation terms, Dr. Yedgar exchanged his warrants for an additional 31,359 Ordinary Shares.

On April 30, 2013, we sold an aggregate of 50,000 Ordinary Shares to Fredric Price, our Director, at a price of \$ 2.00 per share, for total gross proceeds of \$100,000. In connection with such purchase, Mr. Price also received warrants to purchase an aggregate of 25,000 Ordinary Shares, at an exercise price of \$2.00 per share. On September 24, 2013, in connection with the most favored nation terms, Mr. Price exchanged his warrants for an additional 125,438 Ordinary Shares.

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.

As part of an agreement with Saul Yedgar signed in May 2011, the Company paid, in January 2014, approximately \$66,000 for services provided by Dr. Yedgar in his position as Chief Scientific Officer. In December 2013, Dr. Yedgar resigned as Chief Scientific Officer.

C. Interests of Experts and Counsel.

Not applicable.

Item 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

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

B. Legal Proceedings

We are not involved in any material legal proceedings.

C. Dividend Policy

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

D. Significant Changes

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

Item 9. THE OFFER AND LISTING

A. Offering and Listing Details

Price History

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 “CLSDX” from January 3, 2014 to January 30, 2014 and were quoted on the OTCQB under the symbol “CLSDY” 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.

	<u>USD High</u>	<u>USD Low</u>
Fiscal Year Ended		
December 31, 2013	\$ 25.00	\$ 7.10
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
Month Ended		
September 2013	\$ 20.00	\$ 20.00
October 2013	\$ 20.00	\$ 20.00
November 2013	\$ 20.00	\$ 10.00
December 2013	\$ 10.00	\$ 7.10
January 2014	\$ 11.90	\$ 6.06
February 2014	\$ 9.00	\$ 6.45

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.

B. Plan of Distribution

Not applicable.

C. Markets

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 “CLSDX” from January 3, 2014 to January 30, 2014 and were quoted on the OTCQB under the symbol “CLSDY” 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.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

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

C. Material Contracts

Set forth below are summaries of material agreements to which we are a party, other than contracts entered into in the ordinary course of business, that have been in effect since January 1, 2012. In addition to the agreements described below, we also enter into agreements with clinical research organizations, or CROs, for the conduct of our clinical trials. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to this Annual Report.

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 our principal shareholder, Prof. Yedgar, is conducting 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. Our breach of this license or failure to obtain a license to technology required to develop, test and commercialize our products may seriously harm our business.

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.

Research Agreement with Yissum

On June 20, 2005, the Company and Yissum entered into an agreement pursuant to which Yissum will provide the Company research services under the supervision of Prof. Yedgar our Chief Scientific Officer, or the Research Agreement. Prof. Yedgar is a Professor Emeritus and a research lab chief at Yissum, and has no management position, voting power or other significant influence with respect to Yissum. The Research Agreement provides that the research services will be provided in accordance with a schedule as agreed by the parties. The intellectual property and the technology that are developed during the provision of these services will be owned by Yissum, and we have been granted an exclusive, worldwide license and right to the results developed under the Research Agreement, as well as the permission to sublicense such results, in accordance with the conditions of the License Agreement. In consideration for the research services, the Company paid Yissum a total fee of \$90,000, which included research expenses and costs incurred by Yissum.

The service agreement was renewed several times prior to 2011. On February 28, 2011, the service agreement was renewed again. In consideration for the performance of services, we agreed to pay Yissum \$70,000 plus overhead per year, depending on the work requested by us to be done at our sole and exclusive option during each year of the following five years. The additional services fees shall be payable in semi-annual payments.

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 is 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.

Prof. Saul Yedgar. On February 21, 2005, we entered into a consulting agreement with Prof. Yedgar, pursuant to which Prof. Yedgar agreed to render services to us in the field of compound research and development, clinical trials design and other projects as specified by us from time to time in accordance with the board of directors' requirements. This consulting agreement was terminable by either party upon 90 days' prior notice. The agreement included a non-competition provision that prohibited Prof. Yedgar, for a period of six months after the termination of such 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.

The agreement states that no employer-employee relationship shall exist between the parties, and if a competent court rules that such employer-employee relationship exists, Prof. Yedgar agrees to indemnify the Company for up to 45% of the consideration paid to him under the consulting agreement. In consideration for his services, Prof. Yedgar is entitled to a fee of £750 for each working day, up to a maximum of five working days per month (any additional days is subject to our prior approval) and no more than an aggregate of £12,000 in fees per annum.

On February 21, 2005, we entered into an agreement with Professor Yedgar pursuant to which he agreed to act as a director of the Company for an initial term of 24 months. Under that agreement, Professor Yedgar was entitled, with effect from January 1, 2005, until the date on which the Company completed an offering raising up to £1,900,000, to be paid £1,000 for each board meeting he attended, subject to completion of such an offering, plus reimbursement of expenses reasonably incurred by him. The agreement also included standard confidentiality provisions and provisions on non-solicitation of customers and employees of the Company for a period of two years after the termination of his services under that agreement.

On March 14, 2007, we entered into an agreement with Prof. Yedgar for his reappointment as a member of our board of directors. Under that agreement, Prof. Yedgar is entitled to £500 for every meeting he attends. The agreement includes a customary non-compete provision for a period of six months after his resignation or departure from the Company. To date, no amounts have been paid to Prof. Yedgar under this agreement and, on February 22, 2011, Prof. Yedgar agreed to waive all accrued fees owed to him as of such date.

Effective as of May 25, 2011, the consulting agreement described above was terminated and we entered into an employment agreement with Prof. Yedgar, which is governed by English law, pursuant to which he agreed to serve as our Chief Scientific Officer for a period of 60 months. This agreement may be terminated by: (a) either party, upon 30 days' prior notice, or (b) immediately by the Company, under certain circumstances, including material, recurring, continuing or a fundamental breach of his obligations under the agreement and his criminal conviction under certain circumstances. Prof. Yedgar is entitled to a monthly salary of NIS 8,312, or approximately an annual salary of £17,000, plus reimbursement of reasonable out-of-pocket expenses incurred by him in performing his duties once the Company completes its private placement. Our board of directors is authorized to review Prof. Yedgar's salary on annual basis, although it is not obligated to increase it. Prof. Yedgar is also entitled to 20 vacation days per year.

The employment agreement also includes a non-competition covenant that prohibits Prof. Yedgar, for a period of six months after the termination of his employment with us, to be involved in or provide technical, commercial or professional services to any business that competes, or is likely to compete, with our business in the United Kingdom, Israel or the United States. Prof. Yedgar is also obligated to keep confidential the confidential information of our Company.

The employment agreement also requires the approval of our board of directors in connection with the following actions: (a) incurring any capital expenditure in excess of any sum authorized by the board; and (b) obligate the Company, without prior written authorization from the Chief Executive Officer.

Dr. Yedgar resigned as our Chief Scientific Officer on December 8, 2013 and is no longer an executive officer of our company.

April 2012 Financing

On April 4, 2012, we completed a private placement under a Securities Purchase Agreement, dated April 3, 2012, or the April Purchase Agreement, by and among us and certain institutional accredited investors named Iroquois Master Fund, Ltd. and Alpha Capital Anstalt, or the Financing. As part of the April 2012 Financing, we sold an aggregate of \$1.1 million aggregate principal amount of original issue discount senior secured convertible notes, or the Notes and warrants to purchase an aggregate of 643,274 Ordinary Shares, or the April 2012 Warrants, for gross proceeds of \$1.0 million. Such securities were issued in reliance on an exemption from registration pursuant to Section 4(2) and Regulation D of the Securities Act of 1933, as amended.

The April Purchase Agreement contains customary covenants. Furthermore, under the April Purchase Agreement, we were required to file a registration statement pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, on Form 20-F no later than July 4, 2012 and have such Form 20-F declared effective no later than January 4, 2013. The Form 20-F became effective on October 30, 2012 (the "Self Filing Effective Date"). We have agreed to take all necessary actions to have our Ordinary Shares quoted on the OTCBB as promptly as practicable after the Self Filing Effective Date.

Under the April Purchase Agreement, while the April 2012 Warrants are outstanding, we have agreed not to enter into any variable rate transactions, as described in the April Purchase Agreement.

Furthermore, the April Purchase Agreement provides a participation right to the investors in the April 2012 Financing to participate in subsequent financings by us. The April Purchase Agreement also permitted the investors in the Financing to exchange their Notes for securities sold in any subsequent financing, other than certain excluded issuances. If an investor elected to make such an exchange, on a one for one exchange, such investor would receive such securities issued in the subsequent financing that an investor in the subsequent financing would have received for each \$1.00 invested. On January 2, 2013 we repaid in full the convertible notes.

Description of Notes

Under the April Purchase Agreement, we sold to the investors an aggregate of \$1.1 million of Notes. The Notes were issued at an original issue discount of approximately 9%. The Notes had a maturity date of January 4, 2013 and did not bear interest. The Notes were guaranteed by our subsidiaries and are secured on a first-priority basis by substantially all of our assets, including our license agreement with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. and our co-owned patents.

On January 2, 2013 we repaid in full the convertible notes.

Description of April 2012 Warrants

As part of the April 2012 Financing, we issued to the investors warrants to purchase an aggregate of 643,274 Ordinary Shares. The April 2012 Warrants have an initial exercise price of \$1.71 per share, exercisable for a term of five years, subject to adjustment. On and after the April 4, 2013, if a registration statement registering the Ordinary Shares underlying the April 2012 Warrants is not effective, the holders of the April 2012 Warrants may exercise their warrants on a cashless basis. If all the Warrants are exercised for cash, we will receive an aggregate of \$1.1 million.

The exercise price of the April 2012 Warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The exercise price is also subject to "full ratchet" anti-dilution adjustment, similar to the Notes. The convertibility of the April 2012 Warrants may be limited if, upon conversion, the holder thereof would beneficially own more than 4.9% of our Ordinary Shares.

To the extent we enter into a fundamental transaction (as defined in the April 2012 Warrants and which includes, without limitation, our entering into a merger or consolidation with another entity, our selling all or substantially all of our assets, or a person acquiring 50% of our voting shares), the holders will have the option to require us to repurchase the Warrants from the investor at its Black-Scholes value.

Registration Rights Agreement

In the April 2012 Financing, we also entered into a registration rights agreement with the investors pursuant to which we agreed to register the resale of up to 133% of the number of Ordinary Shares that may be acquired by the investors by converting the Notes and exercising their April 2012 Warrants. A registration statement was filed and declared effective by the SEC.

On September 19, 2013, we entered into a Securities Purchase Agreement with certain institutional accredited investors, pursuant to which we agreed to sell, in a private placement, an aggregate of 21,958,302 Ordinary Shares for an aggregate purchase price of \$12,516,232 at \$0.57 per share. As a result of such transaction, the exercise price of the April 2012 Warrants issued in the April 2012 Financing were reduced to \$0.57 per share in accordance with calculations performed by us pursuant to the anti-dilution provisions contained in the April 2012 Financing agreements. The number of warrants issued to the investors increased from 643,274 to 1,929,824.

November 2012 Financing

Description of the November Purchase Agreement

On November 30, 2012, we completed a private placement under the November Purchase Agreement. As part of the November 2012 Financing, we sold 751,500 units, each unit consisting of one Ordinary Share and one warrant to purchase one half of one Ordinary Share at a price of \$2.00 per unit, for aggregate gross proceeds of \$1,503,000. If all of the November 2012 Warrants are exercised, we will receive gross proceeds of \$751,500. Such securities were issued in reliance on an exemption from registration pursuant to Section 4(2) and Regulation D of the Securities Act of 1933, as amended. We offered the securities with the assistance of Garden State Securities Inc. who acted as our non-exclusive placement agent and performed its services on a "best efforts" basis. As part of the compensation paid to Garden State Securities, Inc., we issued them a warrant to purchase up to 90,180 Ordinary shares, which we refer to as the GSS warrant.

Under the terms of the November Purchase Agreement, and subject to certain limitations, from the date each investor entered into the November Purchase Agreement until the earlier of (i) the six month anniversary of the effective date of the registration statement or (ii) the date immediately following the 20 consecutive trading days wherein the trading volume for the Ordinary Shares or ADSs exceeds \$100,000 per trading day, which 20 consecutive trading day period shall have commenced only after the effective date of the registration statement, each investor may elect to exchange all of its shares and warrants for any such additional securities issued by us in a subsequent financing, on the same terms and conditions as such subsequent financing, based in the per share purchase price multiplied by the number of shares being exchanged.

As part of the November 2012 Financing, the Company issued to the investors the November Warrants to purchase Ordinary Shares at an initial exercise price of \$2.00 per share, exercisable for a term of five years. The exercise price is subject to standard anti-dilution adjustments.

Description of the November 2012 Warrants and the GSS Warrant

As part of the November 2012 Financing, we issued to the investors the November 2012 Warrants to purchase an aggregate of 375,750 Ordinary Shares and the GSS Warrants to purchase up to 90,180 Ordinary Shares. The November 2012 Warrants and the GSS Warrants have an initial exercise price of \$2.00 per share, exercisable for a term of five years, subject to adjustment. On and after the November 30, 2013, if a registration statement registering the Ordinary Shares underlying the November 2012 Warrants is not effective, the holders of the November 2012 Warrants may exercise their warrants on a cashless basis. If all the November 2012 Warrants and GSS Warrants are exercised for cash, we will receive an aggregate of \$931,860.

The convertibility of the November 2012 Warrants may be limited if, upon conversion, the holder thereof would beneficially own more than 4.9% of our Ordinary Shares.

To the extent we enter into a fundamental transaction (as defined in the November 2012 Warrants and which includes, without limitation, our entering into a merger or consolidation with another entity, our selling all or substantially all of our assets, or a person acquiring 50% of our voting shares), the holders will have the option to require us to repurchase the Warrants from the investor at its Black-Scholes value.

November Registration Rights Agreement

In the November 2012 Financing, we also entered into the November Registration Rights Agreement with the investors pursuant to which we filed a registration statement to register the resale of up to 133% of the number of Ordinary Shares issued in the November 2012 Financing and that may be issued upon exercise of the November 2012 Warrants. A registration statement was filed and declared effective by the SEC.

2013 Financings

Description of the 2013 Purchase Agreement

On January 17, January 31, and February 28, 2013 ("Closing Dates"), we completed multiple closings of a private placement under the 2013 Purchase Agreement. As part of the 2013 Financing, we sold an aggregate of 495,500 units, each unit consisting of one Ordinary Share and one warrant to purchase one half of one Ordinary Share at a price of \$2.00 per unit, for aggregate gross proceeds of \$991,000. If all of the 2013 Warrants issued to investors are exercised, we will receive gross proceeds of \$1,620,500. Such securities were issued in reliance on an exemption from registration pursuant to Section 4(2) and Regulation D of the Securities Act of 1933, as amended. We offered the securities with the assistance of Garden State Securities Inc. who acted as our non-exclusive placement agent and performed its services on a "best efforts" basis. As part of the compensation paid to Garden State Securities, Inc., we issued GSS and its personnel warrants to purchase up to 53,835 Ordinary shares, which we refer to as the GSS warrant.

Under the terms of the 2013 Purchase Agreement, and subject to certain limitations, from the date each investor entered into the 2013 Purchase Agreement until the later of (i) the two year anniversary of the effective date of this registration statement or (ii) the date immediately following the 20 consecutive trading days wherein the trading volume for the Ordinary Shares or ADSs exceeds \$100,000 per trading day, which 20 consecutive trading day period shall have commenced only after the effective date of the registration statement, each investor may elect to exchange all of its shares and warrants for any such additional securities issued by us in a subsequent financing, on the same terms and conditions as such subsequent financing, based in the per share purchase price multiplied by the number of shares being exchanged, or on a \$1 for \$1 basis, in lieu of cash consideration. Also, as part of the 2013 Financing, the Company issued to the investors the 2013 Warrants to purchase Ordinary Shares at an initial exercise price of \$2.00 per share, exercisable for a term of five years. The exercise price is subject to the same standard anti-dilution adjustments as mentioned above. In addition, while the 2013 Warrants are outstanding if the Company will issue shares or warrants at an effective price per share which is lower than the exercise price of the 2013 Warrants, the exercise price of the 2013 Warrants shall be reduced to the lower share price in the subsequent financing. In addition, until the Expiration Date, the shares and the Series A warrants are also entitled to a price protection.

Description of the 2013 Warrants and the GSS Warrant

As part of the 2013 Financing, we issued to the investors the 2013 Warrants to purchase an aggregate of 810,250 Ordinary Shares and the GSS Warrants to purchase up to 53,835 Ordinary Shares. The 2013 Warrants and the GSS Warrants have an initial exercise price of \$2.00 per share, exercisable for a term of five years, subject to adjustment. On and after the specific Closings Dates, accordingly, if a registration statement registering the Ordinary Shares underlying the November 2012 Warrants is not effective, the holders of the 2013 Warrants may exercise their warrants on a cashless basis. If all the 2013 Warrants and GSS Warrants are exercised for cash, we will receive an aggregate of \$1,728,170.

The Series A Warrants, Series C Warrants and GSS Warrants of the 2013 Financing are exercisable for a term of five years and the Series B Warrants are exercisable until April 2014. The vesting of the Series C warrants is dependent upon exercise of the Series B warrants. The Series C warrants shall become exercisable in proportion to the holder's exercise of the Series B warrant as compared with the total Series B warrants issued to such holder. The exercise price is subject to standard anti-dilution adjustments, including price protection for subsequent warrant sales.

Subject to certain limitations, the Series B Warrants may be cancelled for consideration equal to \$0.001 per Warrant Share by us in the event that the closing sale price of the ordinary shares for each 20 consecutive trading days exceeds \$3.75 (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like) and (ii) the average daily volume for such 20 day period exceeds 75,000 ordinary shares or ADSs (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like).

The exercisability of the warrants may be limited if, upon exercise, the holder thereof would beneficially own more than 4.9% of our ordinary shares.

To the extent we enter into a fundamental transaction (as defined in the 2013 Warrants and which includes, without limitation, our entering into a merger or consolidation with another entity, our selling all or substantially all of our assets, or a person acquiring 50% of our voting shares), the holders will have the option to require us to repurchase the Warrants from the investor at its Black-Scholes value.

2013 Registration Rights Agreement

In the 2013 Financing, we also entered into the 2013 Registration Rights Agreement with the investors pursuant to which we have agreed to file a registration statement to register the resale of up to 133% of the number of Ordinary Shares issued in the 2013 Financing and that may be issued upon exercise of the 2013 Warrants. A registration statement was filed and declared effective by the SEC.

September 2013 Financing

On September 19, 2013, we entered into a Securities Purchase Agreement with certain institutional accredited investors, pursuant to which we agreed to sell, in a private placement, an aggregate of 21,958,302 Ordinary Shares for an aggregate purchase price of \$12,516,232. The closing of the Offering occurred on September 24, 2013 and our placement agents received an aggregate of approximately \$898,000 from us.

As a result of price protection provisions from investment agreements with previous investors, (i) an aggregate of 4,046,692 additional Ordinary Shares are being issued to previous investors in connection with the Offering and (ii) there will be an additional 1,259,092 Ordinary Shares issuable upon exercise of outstanding warrants. All of such shares are being registered for resale hereby.

We also entered into a registration rights agreement with the investors pursuant to which we agreed to file a registration statement to register the resale of the Ordinary Shares issued in the private placement no later than the 30th day after the Closing Date. We agreed to cause the registration statement to be declared effective within 60 calendar days after the Closing Date, or within 120 calendar days after the Closing Date in the event the Registration Statement is reviewed by the SEC (the "Effective Date"). To the extent the registration statement is not filed by the filing deadline or declared effective by the agreed upon effectiveness deadline, we agreed to pay to each investor holding registrable securities an amount in cash equal to one and one half percent (1.5%) of such investor's original investment amount on the date of such failure and on every 30-day anniversary of such failure until such failure has been cured, pro rated for periods totaling less than 30 days. In the event we fail to make such payments in a timely manner, such payments will bear interest at the rate of 1.0% per month (prorated for partial months) until paid in full.

D. Exchange Controls

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

E. Taxation

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

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

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

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

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

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

United Kingdom tax considerations

Taxation of dividends

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

Taxation of Capital Gains

Subject to the comments in the following paragraph, a holder of Celsus Ordinary Shares or ADSs who, for U.K. tax purposes, is neither resident nor, in the case of an individual, ordinarily resident, in the U.K. will not be liable for U.K. taxation on capital gains realized on the disposal of Celsus Ordinary Shares or ADS unless at the time of the disposal:

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

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

Inheritance Tax

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

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

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

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

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

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

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

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

United States federal income taxation considerations

U.S. Taxation of Distributions

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

in his Celsus Ordinary Shares or ADSs and then, to the extent such distribution exceeds such U.S. Holder's tax basis, it will be treated as capital gain.

Subject to applicable holding period and other limitations, the U.S. Dollar amount of dividends received on the Celsus Ordinary Shares or ADSs by certain non-corporate U.S. Holders are currently subject to taxation at a maximum rate of 15% if the dividends are “qualified dividends” and certain other requirements are met. Dividends paid on the Celsus Ordinary Shares or ADSs will be treated as qualified dividends if: (i) we are eligible for the benefits of the Treaty or the Ordinary Shares or ADSs are readily tradable on an established U.S. securities market and (ii) we were not, in the year prior to the year in which the dividend was paid, and are not, in the year in which the dividend is paid, a passive foreign investment company, or PFIC. Although we currently believe that distributions on the Celsus Ordinary Shares or ADSs that are treated as dividends for U.S. federal income tax purposes should constitute qualified dividends, no assurance can be given that this will be the case. U.S. Holders should consult their tax advisors regarding the tax rate applicable to dividends received by them with respect to the Celsus Ordinary Shares or ADSs, as well as the potential treatment of any loss on a disposition of Celsus Ordinary Shares or ADSs as long-term capital loss regardless of the U.S. Holders’ actual holding period for the Celsus Ordinary Shares or ADSs.

The 15% maximum individual tax rate for qualified dividends is scheduled to expire at the end of 2012, after which all dividends would be subject to ordinary income tax rates. The maximum rate for ordinary income for individuals, currently 35%, is scheduled to increase to 39.6% in 2013.

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

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

U.S. Taxation of Capital Gains

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

The maximum individual rate for long-term capital gain is currently 15%. This rate is scheduled to increase to 20% after 2012.

Medicare Tax

For taxable years beginning after 2012, individuals, estates and trusts will be subject to a Medicare tax of 3.8% on “net investment income,” including in particular dividends, interest, and capital gain from the sale of investment securities. The Medicare tax will apply to the lesser of such net investment income or the excess of the taxpayer’s adjusted gross income (with certain modifications) over a specified amount. The specified amount is \$250,000 for married individuals filing jointly, \$125,000 for married individuals filing separately, and \$200,000 for single individuals.

Passive foreign investment company rules

We believe that we may be treated as a PFIC for U.S. federal income tax purposes for the current taxable year and in future years.

We would be a PFIC for U.S. federal income tax purposes in any taxable year if 75% or more of our gross income would be passive income, or on average at least 50% of the gross value of our assets is held for the production of, or produces, passive income. In making the above determination, we are treated as earning our proportionate share of any income and owning our proportionate share of any asset of any company in which we are considered to own, directly or indirectly, 25% or more of the shares by value. If we were considered a PFIC at any time when a U.S. Holder held Celsus Ordinary Shares or ADSs, we generally should continue to be treated as a PFIC with respect to that U.S. Holder, and the U.S. Holder generally will be subject to special rules with respect to (a) any gain realized on the disposition of the Celsus Ordinary Shares or ADSs and (b) any “excess distribution” by us to the U.S. Holder in respect of the Celsus Ordinary Shares or ADSs. Under the PFIC rules: (i) the gain or excess distribution would be allocated ratably over the U.S. Holder’s holding period for the Celsus Ordinary Shares or ADSs, (ii) the amount allocated to the taxable year in which the gain or excess distribution was realized or to any year before we became a PFIC would be taxable as ordinary income and (iii) the amount allocated to each other taxable year would be subject to tax at the highest tax rate in effect in that year and an interest charge generally applicable to underpayments of tax would be imposed in respect of the tax attributable to each such year. Because a U.S. Holder that is a direct (and in certain cases indirect) shareholder of a PFIC is deemed to own its proportionate share of interests in any lower-tier PFICs, U.S. Holders should be subject to the foregoing rules with respect to any of our subsidiaries characterized as PFICs, if we are deemed a PFIC. A U.S. Holder may be able to avoid many of these adverse tax consequences if it elects to mark the Celsus Ordinary Shares or ADSs to market on an annual basis. However, any such mark to market election would not be available for a lower-tier PFIC. U.S. Holders are urged to consult their tax advisors about the PFIC rules, including the advisability, procedure and timing of making a mark-to-market election and the U.S. Holder’s eligibility to file such an election (including whether the Celsus Ordinary Shares or ADSs are treated as “publicly traded” for such purpose).

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

Information reporting and backup withholding

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

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

Pursuant to the Hiring Incentives to Restore Employment Act enacted on March 18, 2010, an individual U.S. Holder may be required to submit to the IRS certain information with respect to his or her beneficial ownership of Celsus Ordinary Shares or ADSs, unless such Ordinary Shares or ADSs are held on his or her behalf by a financial institution, as defined in Section 6038D of the Code. The new law also imposes penalties if an individual U.S. Holder is required to submit such information to the IRS and fails to do so. U.S. Holders should consult their own tax advisors regarding the application of the new law in their particular circumstances.

Transfer of ADSs

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

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

I. Subsidiary Information

Not applicable.

Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT RISK

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

Risk Management Framework

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

Currency Exchange Rate Sensitivity

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

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

Interest Rate Sensitivity

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

Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

American Depositary Shares

Deutsche Bank Trust Company Americas, as depositary, will register and deliver the ADSs. Each ADS will represent ownership of ten (10) Ordinary Shares deposited with State Street Bank & Trust Company, having its principal office at 525 Ferry Road, Crewe Toll, Edinburgh, EH5 2AW Scotland, as custodian for the depositary. Each ADS will also represent ownership of any other securities, cash or other property which may be held by the depositary. The depositary's corporate trust office at which the ADSs will be administered is located at 60 Wall Street, New York, NY 10005, USA. The principal executive office of the depositary is located at 60 Wall Street, New York, NY 10005, USA.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, or DTC, pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depositary to the ADS holders entitled thereto.

We will not treat ADS holders as our shareholders and accordingly, you, as an ADS holder, will not have shareholder rights. English law governs shareholder rights. The depositary will be the holder of the Ordinary Shares underlying your ADSs. As a holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and you, as an ADS holder, and the beneficial owners of ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. The laws of the State of New York govern the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American Depositary Receipt.

Holding the ADSs

How will you hold your ADSs?

You may hold ADSs either (1) directly (a) by having an American Depositary Receipt, or ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (b) by holding ADSs in the DRS, or (2) indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADS holder. This description assumes you hold your ADSs directly. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of Ordinary Shares your ADSs represent as of the record date (which will be as close as practicable to the record date for our Ordinary Shares) set by the depositary with respect to the ADSs.

- **Cash.** The depositary will convert any cash dividend or other cash distribution we pay on the Ordinary Shares or any net proceeds from the sale of any Ordinary Shares, rights, securities or other entitlements into U.S. dollars if it can do so on a reasonable basis, and can transfer the U.S. dollars to the United States. If that is not possible or lawful or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.
- Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary, that must be paid, will be deducted. See “Taxation.” It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.*
- **Shares.** The depositary may distribute additional ADSs representing any Ordinary Shares we distribute as a dividend or free distribution to the extent reasonably practicable and permissible under law. The depositary will only distribute whole ADSs. It will try to sell Ordinary Shares which would require it to deliver a fractional ADS and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new Ordinary Shares. The depositary may sell a portion of the distributed Ordinary Shares sufficient to pay its fees and expenses in connection with that distribution.
- **Elective Distributions in Cash or Shares.** If we offer holders of our Ordinary Shares the option to receive dividends in either cash or shares, the depositary, after consultation with us and having received timely notice as described in the deposit agreement of such elective distribution by us, has discretion to determine to what extent such elective distribution will be made available to you as a holder of the ADSs. We must first instruct the depositary to make such elective distribution available to you and furnish it with satisfactory evidence that it is legal to do so. The depositary could decide it is not legal or reasonably practical to make such elective distribution available to you, or it could decide that it is only legal or reasonably practical to make such elective distribution available to some but not all holders of the ADSs. In such case, the depositary shall, on the basis of the same determination as is made in respect of the Ordinary Shares for which no election is made, distribute either cash in the same way as it does in a cash distribution, or additional ADSs representing Ordinary Shares in the same way as it does in a share distribution. The depositary is not obligated to make available to you a method to receive the elective dividend in shares rather than in ADSs. There can be no assurance that you will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of Ordinary Shares.
- **Rights to Purchase Additional Shares.** If we offer holders of our Ordinary Shares any rights to subscribe for additional shares or any other rights, the depositary may after consultation with us and having received timely notice as described in the deposit agreement of such distribution by us, make these rights available to you. We must first instruct the depositary to make such rights available to you and furnish the depositary with satisfactory evidence that it is legal to do so. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the net proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them. If the depositary makes rights available to you, it will exercise the rights and purchase the shares on your behalf. The depositary will then deposit the shares and deliver ADSs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay. U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

- **Other Distributions.** Subject to receipt of timely notice from us with the request to make any such distribution available to you, and provided the depositary has determined such distribution is lawful and reasonably practicable and feasible and in accordance with the terms of the deposit agreement, the depositary will send to you anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice: it may decide to sell what we distributed and distribute the net proceeds in the same way as it does with cash; or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to you unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.
- The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposit Ordinary Shares or evidence of rights to receive Ordinary Shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons entitled thereto.

How do ADS holders cancel an American Depositary Share?

You may turn in your ADSs at the depositary's corporate trust office or by providing appropriate instructions to your broker. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the Ordinary Shares and any other deposited securities underlying the ADSs to you or a person you designate at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, if feasible.

The depositary may refuse to accept for surrender ADSs only in the case of (i) temporary delays caused by closing our transfer books or those of the depositary or the deposit of our Ordinary Shares in connection with voting at a shareholders' meeting or the payment of dividends, (ii) the payment of fees, taxes and similar charges and (iii) compliance with any laws or governmental regulations relating to depositary receipts or to the withdrawal of deposited securities. Subject thereto, in the case of surrender of a number of ADSs representing other than a whole number of our Ordinary Shares, the depositary will cause ownership of the appropriate whole number of our Ordinary Shares to be delivered in accordance with the terms of the deposit agreement and will, at the discretion of the depositary, either (i) issue and deliver to the person surrendering such ADSs a new ADS representing any remaining fractional Ordinary Share or (ii) sell or cause to be sold the fractional Ordinary Shares represented by the ADSs surrendered and remit the proceeds of such sale (net of applicable fees and charges of, and expenses incurred by, the depositary and taxes and/or governmental charges) to the person surrendering the ADS.

How do ADS holders interchange between Certificated ADSs and Uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send you a statement confirming that you are the owner of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to you an ADR evidencing those ADSs.

Voting Rights

How do you vote?

You may instruct the depositary to vote the deposited securities. Otherwise, you could exercise your right to vote directly if you withdraw the Ordinary Shares your ADSs represent. However, you may not know about the meeting enough in advance to withdraw the Ordinary Shares.

If we ask for your instructions and upon timely notice from us as described in the deposit agreement, the depositary will notify you of the upcoming vote and arrange to deliver our voting materials to you. The materials will (1) describe the matters to be voted on and (2) explain how you may instruct the depositary to vote the Ordinary Shares or other deposited securities underlying your ADSs as you direct, including an express indication that such instruction may be given or deemed given in accordance with the second to last sentence of this paragraph if no instruction is received, to the depositary to give a discretionary proxy to a person designated by us. Voting instructions may be given only by mail and in respect of a number of ADSs representing an integral number of our Ordinary Shares or other deposited securities. For instructions to be valid, the depositary must receive them on or before the date specified. The depositary will try, as far as practical, subject to the laws of the United Kingdom and the provisions of our constitutive documents, to vote or to have its agents vote the Ordinary Shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct. If we timely requested the depositary to solicit your instructions but no instructions are received by the depositary from an owner with respect to any of the deposited securities represented by the ADSs of that owner on or before the date established by the depositary for such purpose, the depositary shall deem that owner to have instructed the depositary to give a discretionary proxy to a person designated by us with respect to such deposited securities, and the depositary shall give a discretionary proxy to a person designated by us to vote such deposited securities. However, no such instruction shall be deemed given and no such discretionary proxy shall be given with respect to any matter if we inform the depositary we do not wish such proxy given, substantial opposition exists or the matter materially and adversely affects the rights of holders of the Ordinary Shares.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the Ordinary Shares underlying your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and you may have no recourse if the Ordinary Shares underlying your ADSs are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we are required to give the depositary 30 days' advance notice of any such meeting and details concerning the matters to be voted upon sufficiently in advance of the meeting date, and the depositary will mail you a notice.

Fees and Charges

As a holder of American Depositary Shares, or ADSs, you will be required to pay the following service fees to the depositary bank:

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

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

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

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

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

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

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

Payment of Taxes

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

Reclassifications, Recapitalizations and Mergers

<u>If we:</u>	<u>Then:</u>
Change the nominal or par value of our Ordinary Shares	The cash, shares or other securities received by the depositary will become deposited securities.
Reclassify, split up or consolidate any of the deposited securities	Each ADS will automatically represent its equal share of the new deposited securities.
Distribute securities on the Ordinary Shares that are not distributed to you or Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action	The depositary may distribute some or all of the cash, shares or other securities it received. It may also deliver new ADSs or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the form of ADR without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, including expenses incurred in connection with foreign exchange control regulations and other charges specifically payable by ADS holders under the deposit agreement, or materially prejudices a substantial existing right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement if we ask it to do so, in which case the depositary will give notice to you at least 90 days prior to termination. The depositary may also terminate the deposit agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary within 90 days. In such case, the depositary must notify you at least 30 days before termination.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property and deliver Ordinary Shares and other deposited securities upon cancellation of ADSs after payment of any fees, charges, taxes or other governmental charges. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. The depositary's only obligations will be to account for the money and other cash. After termination, our only obligations will be to indemnify the depositary and to pay fees and expenses of the depositary that we agreed to pay.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary will maintain facilities in New York to record and process the issuance, cancellation, combination, split-up and transfer of ADRs.

These facilities may be closed from time to time, to the extent not prohibited by law or if any such action is deemed necessary or advisable by the depositary or us, in good faith, at any time or from time to time because of any requirement of law, any government or governmental body or commission or any securities exchange on which the ADRs or ADSs are listed, or under any provision of the deposit agreement or provisions of, or governing, the deposited securities, or any meeting of our shareholders or for any other reason.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without gross negligence or willful misconduct;
- are not liable if either of us is prevented or delayed by law or circumstances beyond our control from performing our obligations under the deposit agreement, including, without limitation, requirements of any present or future law, regulation, governmental or regulatory authority or share exchange of any applicable jurisdiction, any present or future provisions of our memorandum and articles of association, on account of possible civil or criminal penalties or restraint, any provisions of or governing the deposited securities or any act of God, war or other circumstances beyond our control as set forth in the deposit agreement;
- are not liable if either of us exercises, or fails to exercise, discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other party;
- may rely upon any documents we believe in good faith to be genuine and to have been signed or presented by the proper party;
- disclaim any liability for any action/inaction in reliance on the advice or information of legal counsel, accountants, any person presenting Ordinary Shares for deposit, holders and beneficial owners (or authorized representatives) of ADSs, or any person believed in good faith to be competent to give such advice or information;
- disclaim any liability for inability of any holder to benefit from any distribution, offering, right or other benefit made available to holders of deposited securities but not made available to holders of ADSs; and
- disclaim any liability for any indirect, special, punitive or consequential damages.

The depositary and any of its agents also disclaim any liability for any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the deposit agreement, the failure or timeliness of any notice from us, the content of any information submitted to it by us for distribution to you or for any inaccuracy of any translation thereof, any investment risk associated with the acquisition of an interest in the deposited securities, the validity or worth of the deposited securities, the credit-worthiness of any third party, or for any tax consequences that may result from ownership of ADSs, Ordinary Shares or deposited securities.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will issue, deliver or register a transfer of an ADS, make a distribution on an ADS, or permit withdrawal of Ordinary Shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any Ordinary Shares or other deposited securities and payment of the applicable fees, expenses and charges of the depositary;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to issue and deliver ADSs or register transfers of ADSs generally when the register of the depositary or our transfer books are closed or at any time if the depositary or we think it is necessary or advisable to do so.

Your Right to Receive the Shares Underlying Your ADSs

You have the right to cancel your ADSs and withdraw the underlying Ordinary Shares at any time except:

- when temporary delays arise because: (1) the depository has closed its transfer books or we have closed our transfer books; (2) the transfer of Ordinary Shares is blocked to permit voting at a shareholders' meeting; or (3) we are paying a dividend on our Ordinary Shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of Ordinary Shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depository to deliver ADSs before deposit of the underlying Ordinary Shares. This is called a pre-release of the ADSs. The depository may also deliver Ordinary Shares upon cancellation of pre-released ADSs (even if the ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying Ordinary Shares are delivered to the depository. The depository may receive ADSs instead of Ordinary Shares to close out a pre-release. The depository may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depository in writing that it or its customer (a) owns the Ordinary Shares or ADSs to be deposited, (b) assigns all beneficial rights, title and interest in such Ordinary Shares or ADSs to the depository for the benefit of the owners, (c) will not take any action with respect to such Ordinary Shares or ADSs that is inconsistent with the transfer of beneficial ownership, (d) indicates the depository as owner of such Ordinary Shares or ADSs in its records, and (e) unconditionally guarantees to deliver such Ordinary Shares or ADSs to the depository or the custodian, as the case may be; (2) the pre-release is fully collateralized with cash or other collateral that the depository considers appropriate; and (3) the depository must be able to close out the pre-release on not more than five business days' notice. Each pre-release is subject to further indemnities and credit regulations as the depository considers appropriate. In addition, the depository will normally limit the number of ADSs that may be outstanding at any time as a result of pre-release to 30% of the aggregate number of ADSs then outstanding, although the depository, in its sole discretion, may disregard the limit from time to time, if it thinks it is appropriate to do so, including (1) due to a decrease in the aggregate number of ADSs outstanding that causes existing pre-release transactions to temporarily exceed the limit stated above or (2) where otherwise required by market conditions. The depository may also set limits with respect to the number of ADSs and Shares involved in pre-release transactions with any one person on a case-by-case basis as it deems appropriate.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC pursuant to which the depository may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depository to the ADS holders entitled thereto. Profile is a required feature of DRS which allows a DTC participant, claiming to act on behalf of an ADS holder, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register such transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not verify, determine or otherwise ascertain that the DTC participant which is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on, and compliance with, instructions received by the depository through the DRS/Profile System and in accordance with the deposit agreement, shall not constitute negligence or bad faith on the part of the depository.

PART II

Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

A. Defaults

None.

B. Arrears and Delinquencies

None.

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

Not applicable.

Item 15. CONTROLS AND PROCEDURES**(a) Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 20-F, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

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

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013, based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2013.

(c) Attestation Report of Registered Public Accounting Firm

Not Applicable.

(d) Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [RESERVED]**Item 16A. Audit Committee Financial Expert**

Our board of directors has determined that Mr. Allan Shaw is the audit committee financial expert.

Item 16B. Code of Ethics

In March 2013, our Board of Directors adopted a Code of Business Conduct and Ethics that applies to all our employees, including without limitation, our chief executive officer, chief financial officer and other executive officers. A copy of our Company's Code of Business Conduct and Ethics may be viewed on our website at www.celsustx.com. A copy of our Code may be obtained, without charge, upon a written request addressed to our investor relations department, e-mail address at : ir@celsustx.com.

Item 16C. Principal Accountant Fees and Services

The following table sets forth, for each of the years indicated, the fees billed by our independent registered public accounting firm.

Services Rendered	Year Ended December 31,	
	2012	2013
	(in thousands of US dollars)	
Audit (1)	\$ 110	\$ 154
Audit related services (2)	\$ —	\$ -
Tax (3)	—	—
Total	\$ 110	\$ 154

- (1) Audit of the consolidated financial statements, audit of statutory financial statements, interim review procedures and the review of documents filed with the SEC.
- (2) Audit related services relate to work regarding a public listing or offering.
- (3) Tax fees relate to tax compliance, planning and advice.

Pre-Approval policies and procedures

The Audit Committee recognizes it is important that the independence of the external auditors, real or perceived, is not impaired through the provision of non-audit services. To ensure the independence and objectivity of the external auditors, all service are pre- approved by the Audit Committee.

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

Not applicable.

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

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

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

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

- Independent Director Oversight of Director Nominations which requires independent director involvement in the selection of director nominees, by having a Nominations Committee comprised solely of independent directors, and
- Company By-Laws providing for a quorum of at least 33 1/3 percent of the outstanding shares of the Company's common voting stock.

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

In accordance with our Nasdaq listing, our Audit Committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our Audit Committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the Audit Committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

Item 16H. Mine Safety Disclosures

Not applicable.

PART III

Item 17. FINANCIAL STATEMENTS

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

Item 18. FINANCIAL STATEMENTS

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

Item 19. EXHIBITS

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Exhibit Description</u>
2.1*	Celsus Therapeutics PLC, Memorandum of Association
2.2§§	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
4.10*	Exclusive License Agreement, dated as of November 27, 2002, by and between Celsus Biopharmaceuticals, Inc. and Yissum Research Development Company of the Hebrew University of Jerusalem
4.11*	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
4.12*	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
4.13*	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
4.14*	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

- 4.15* Fifth Extension Agreement for Rendering of Services, dated as of February 22, 2011, by and between the Registrant and Yisum Research Development Company of the Hebrew University of Jerusalem
- 4.16** Director Agreement, dated as of June 16, 2005, between the Registrant and Gilead Raday
- 4.17** Amendment to Director Agreement, dated as of March 14, 2007, between the Registrant and Gilead Raday
- 4.18** Chairman Agreement, dated as of February 18, 2005, between the Registrant and Mark Cohen
- 4.19** Director Agreement, dated as of August 28, 2007, between the Registrant and Dr. Johnson Lau
- 4.20** Director Agreement, dated as of August 28, 2007, between the Registrant and Dr. David Sidransky
- 4.21** Director Agreement, dated as of February 21, 2005 between the Registrant and Prof. Saul Yedgar
- 4.22* Amendment to Director Agreement, dated as of March 14, 2007, between the Registrant and Prof. Saul Yedgar
- 4.23* Employment Agreement, dated as of January 11, 2012, between Dov Elefant and the Registrant
- 4.24§§ Employment Agreement, dated as of October 23, 2013, between Dr. Pablo Jimenez and the Registrant
- 4.25* Amended and Restated 2007 Stock Option Plan, dated April 26, 2012
- 4.26* Second Amendment to Amended and Restated 2007 Stock Option Plan, dated June 20, 2012
- 4.27** Securities Purchase Agreement dated April 3, 2012 by and between Registrant and the buyers listed on the Schedule of Buyers
- 4.28** Sub-License Agreement dated February 1, 2005
- 4.29### Form of Securities Purchase Agreement dated November 30, 2012 by and among Registrant and the buyers signatory thereto
- 4.30### Registration Rights Agreement dated November 30, 2012 by and among Registrant and the Buyers signatory thereto
- 4.31# Form of Securities Purchase Agreement dated January 17, January 31 and February 28, 2013, by and among Registrant and the buyers signatory thereto
- 4.32# Registration Rights Agreement dated January 17, January 31 and February 28, 2013, by and among the Registrant and the Buyers signatory thereto
- 4.33# Employment Agreement, dated as of March 4, 2013, between Gur Roshwalb, M.D. and the Registrant
- 4.34# Form of Financing Subscription Agreement between the Registrant and Mark Cohen (including Form of Warrant) dated December 30, 2012
- 4.35# Form of Financing Subscription Agreement between the Registrant and Mark Cohen (including Form of Warrant) dated January 31, 2013
- 4.36# Form of Financing Subscription Agreement between the Registrant and Saul Yedgar (including Form of Warrant) dated April 3, 2013
- 4.37§ Form of Securities Purchase Agreement, dated as of September 19, 2013, by and among the Registrant and the purchasers named therein
- 4.38§ Form of Registration Rights Agreement, dated as of September 19, 2013, by and among the Registrant and the purchasers named therein
- 4.39** Consulting Agreement, dated as of February 21, 2005, between the Registrant and Prof. Saul Yedgar

4.40**	Employment Agreement, dated as of May 25, 2011, between the Registrant and Prof. Saul Yedgar
8.1*	List of subsidiaries
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1	Consent of independent registered public accounting firm for the Registrant
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 October 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.

SIGNATURES

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

Celsus Therapeutics PLC

By: /s/ Gur Roshwalb

Name: Gur Roshwalb

Title: Chief Executive Officer

Date: March 24, 2014

**CELSUS THERAPEUTICS PLC.
(FORMERLY MORRIA BIOPHARMACEUTICALS PLC.)
(A Development Stage Company)**

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2013

U.S. DOLLARS IN THOUSANDS

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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.
(FORMERLY MORRIA BIOPHARMACEUTICALS PLC.)
(A Development Stage Company)**

We have audited the accompanying consolidated balance sheets of Celsus Therapeutics Plc. (formerly Morria Biopharmaceuticals PLC.) (a development stage company) (the "Company") and its subsidiaries as of December 31, 2013 and 2012, and the related consolidated statement of comprehensive loss, changes in shareholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and the consolidated results of their comprehensive loss and their cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

Tel-Aviv, Israel
March 24, 2014

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	<u>December 31,</u>	
	<u>2013</u>	<u>2012</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 7,657	\$ 1,104
Accounts receivable and prepaid expenses	<u>175</u>	<u>14</u>
Total current assets	<u>7,832</u>	<u>1,118</u>
PROPERTY AND EQUIPMENT, NET	<u>-</u>	<u>2</u>
Total assets	<u>\$ 7,832</u>	<u>\$ 1,120</u>

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2013	2012
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 652	\$ 1,697
Other accounts payable	579	1,255
Short-term convertible notes	-	898
Total current liabilities	1,231	3,850
LONG-TERM LIABILITIES:		
Liability related to stock options and warrants	787	630
Total long-term liabilities	787	630
SHAREHOLDERS' EQUITY (DEFICIENCY):		
Ordinary shares of £ 0.01 par value -		
Authorized: 49,800,000 shares at December 31, 2013 and 2012; Issued and outstanding: 40,227,953 and 13,369,809 shares at December 31, 2013 and 2012, respectively	675	245
Additional paid-in capital	25,681	13,199
Receipts on account of shares	-	118
Deficit accumulated during the development stage	(20,542)	(16,922)
Total shareholders' equity (deficiency)	5,814	(3,360)
Total liabilities and shareholders' equity	\$ 7,832	\$ 1,120

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,			Period from October 7, 2004 (date of inception) to December 31, 2013
	2013	2012	2011	(Unaudited)
Research and development expenses	\$ 1,276	\$ 1,483	\$ 841	\$ 7,116
General and administrative expenses	2,330	2,184	1,406	10,169
Operating loss	3,606	3,667	2,247	17,285
Financial expense (income), net	14	601	(128)	3,224
Net loss	<u>\$ 3,620</u>	<u>\$ 4,268</u>	<u>\$ 2,119</u>	<u>\$ 20,509</u>
Deemed dividend related to warrants modification	-	33	-	33
Net loss attributable to holders of ordinary shares	<u>\$ 3,620</u>	<u>\$ 4,301</u>	<u>\$ 2,119</u>	<u>\$ 20,542</u>
Net basic and diluted loss per share	<u>\$ (0.17)</u>	<u>\$ (0.35)</u>	<u>\$ (0.18)</u>	
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	<u>21,075,065</u>	<u>12,458,874</u>	<u>11,920,562</u>	

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	Deficit accumulated during the development stage	Total
	Number	Amount				
Balance as of October 7, 2004 (date of inception)	-	\$ -	\$ -	\$ -	\$ -	\$ -
Issuance of shares (\$ 0.02-\$ 1.13 per share)	9,977,700	187	3,406	-	-	3,593
Share based compensation	-	-	119	-	-	119
Net loss	-	-	-	-	(2,479)	(2,479)
Balance as of December 31, 2005 (unaudited)	9,977,700	187	3,525	-	(2,479)	1,233
Share based compensation	-	-	69	-	-	69
Net loss	-	-	-	-	(1,769)	(1,769)
Balance as of December 31, 2006 (unaudited)	9,977,700	187	3,594	-	(4,248)	(467)
Waiver of related party shares	(1,070,000)	(22)	22	-	-	-*)
Issuance of share capital, net (\$ 1.58 per share)	2,000,000	40	3,051	-	-	3,091
Share based compensation	-	-	448	-	-	448
Net loss	-	-	-	-	(3,132)	(3,132)
Balance as of December 31, 2007 (unaudited)	10,907,700	205	7,115	-	(7,380)	(60)
Issuance of share capital, net (\$ 1.58-\$ 1.59 per share)	42,996	1	68	-	-	69
Share based compensation	-	-	168	-	-	168
Net loss	-	-	-	-	(1,435)	(1,435)
Balance as of December 31, 2008 (unaudited)	10,950,696	206	7,351	-	(8,815)	(1,258)
Issuance of share capital, net (\$ 1.16-\$ 1.32 per share)	410,097	7	492	-	-	499
Share based compensation	-	-	70	-	-	70
Net loss	-	-	-	-	(1,012)	(1,012)
Balance as of December 31, 2009	11,360,793	213	7,913	-	(9,827)	(1,701)

*) Represents an amount lower than \$ 1.

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

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	Deficit accumulated during the development stage	Total
	Number	Amount				
Balance as of December 31, 2009	11,360,793	213	7,913	-	(9,827)	(1,701)
Issuance of share capital, net (\$ 1.43-\$ 1.57 per share)	200,778	3	309	-	-	312
Receipt on account of shares	-	-	-	60	-	60
Net loss	-	-	-	-	(675)	(675)
Balance as of December 31, 2010	11,561,571	216	8,222	60	(10,502)	(2,004)
Issuance of share capital, net (\$ 1.63-\$ 1.95 per share)	522,026	9	981	(60)	-	930
Exercise of stock options	15,000	*)	-	-	-	*)
Share based compensation	-	-	140	-	-	140
Receipts on account of shares	-	-	-	75	-	75
Expiration of deferred shares and liability related to stock options	-	-	420	-	-	420
Directors fee waiver	-	-	73	-	-	73
Net loss	-	-	-	-	(2,119)	(2,119)
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	<u>13,369,809</u>	<u>\$ 245</u>	<u>\$ 13,199</u>	<u>\$ 118</u>	<u>\$ (16,922)</u>	<u>\$ (3,360)</u>

*) Represents an amount lower than \$ 1.

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

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	Deficit accumulated during the development stage	Total
	Number	Amount				
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	<u>40,227,953</u>	<u>\$ 675</u>	<u>\$ 25,681</u>	<u>\$ -</u>	<u>\$ (20,542)</u>	<u>\$ 5,814</u>

*) Represents an amount lower than \$ 1.

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

CELSUS THERAPEUTICS PLC.
(Formerly: Morria Biopharmaceuticals Plc.)
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,			Period from October 7, 2004 (date of inception) to December 31,
	2013	2012	2011	2013 (Unaudited)
Cash flows from operating activities:				
Net loss	\$ (3,620)	\$ (4,268)	\$ (2,119)	\$ (20,509)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share based compensation and issuance of shares granted to service provider	94	514	140	1,622
Depreciation	2	2	-	10
Changes in values of deferred shares and liability related to stock options and warrants	(286)	(418)	(120)	(8)
Decrease (increase) in accounts receivable and prepaid expenses	(161)	7	4	(175)
Increase (decrease) in trade payables	(1,045)	627	612	965
Increase (decrease) in other accounts payable	(676)	394	475	648
Accrued interest expenses and issuance costs	242	1,008	-	1,250
Net cash used in operating activities	<u>(5,450)</u>	<u>(2,134)</u>	<u>(1,008)</u>	<u>(16,197)</u>
Cash flows from investing activities:				
Purchase of property and equipment	-	-	-	(10)
Net cash used in investing activities	<u>-</u>	<u>-</u>	<u>-</u>	<u>(10)</u>
Cash flows from financing activities:				
Proceeds from issuance of shares and warrants, net	13,103	2,224	930	23,821
Proceeds from issuance of convertible notes and warrants, net	-	890	-	890
Repayment of convertible notes	(1,100)	-	-	(1,100)
Receipts on account of shares	-	118	75	253
Net cash provided by financing activities	<u>12,003</u>	<u>3,232</u>	<u>1,005</u>	<u>23,864</u>
Increase (decrease) in cash and cash equivalents	6,553	1,098	(3)	7,657
Cash and cash equivalents at the beginning of the period	1,104	6	9	-
Cash and cash equivalents at the end of the period	<u>\$ 7,657</u>	<u>\$ 1,104</u>	<u>\$ 6</u>	<u>\$ 7,657</u>
Supplemental disclosure of non-cash investing and financing activities:				
Expiration of deferred shares	\$ -	\$ 128	\$ 420	\$ 548
Director fee waiver	\$ -	\$ -	\$ 73	\$ 73
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 utilization and expiration of most favored nation terms	\$ 27	\$ 141	\$ -	\$ 168
Purchase of property and equipment	\$ -	\$ 4	\$ -	\$ 4
Disposal of property and equipment	\$ 3	\$ -	\$ -	\$ 3
Conversion of trade payables into warrants	\$ -	\$ 309	\$ -	\$ 309

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. (Formerly Morria Biopharmaceuticals Plc.) (the "Company") (a development stage 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 severe chronic inflammatory conditions such as contact dermatitis, etc.

During 2013, the Company changed its corporate name to Celsus Therapeutics Plc.

In February 2013, the Company listed its securities on the Over-the-Counter Bulletin Board (the "OTCQB"). Subsequent to the balance sheet date, the Company up listed to the NASDAQ Capital Market (see Note 15a).

- 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 and the sublicense agreement see Note 8).
- 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. As of December 31, 2013, the Company has accumulated losses in the total amount of \$ 20,542 and has negative cash flow from operating activity in 2013 in the total amount of \$ 16,197.

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. If the Company will not have sufficient liquidity resources, the Company may not be able to continue the development of all of its products or may be required to delay part of the development programs.

The Company's inability to raise funds to carry its research and development activities will have severe negative impact on its ability to remain a viable company beyond June, 2015. The Company is addressing its liquidity issues by implementing initiatives to raise additional funds as well as other measures.

Subsequent to the balance sheet date, the Company raised capital and received gross proceeds of \$ 9,200 (excluding approximately \$ 1,100 of issuance costs) in consideration for the issuance of ordinary shares, as described in more detail in Note 15a.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1:- GENERAL (CONT.)

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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. 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

f. 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, 2013, 2012 and 2011, no impairment losses have been identified.

g. 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.

h. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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, 2013, 2012 and 2011, the Company does not hold provision for uncertain tax positions.

i. 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.

j. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of Ordinary shares outstanding during each year. Diluted net loss per share is computed based on the weighted average number of Ordinary shares outstanding during each year plus dilutive potential equivalent Ordinary shares considered outstanding during the year, in accordance with ASC 260, "Earnings per Share."

All outstanding stock options, deferred shares and warrants have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented. The total number of shares related to outstanding stock options excluded from the calculations of diluted net loss per share was 2,256,690, 823,990 and 411,002 for the years ended December 31, 2013, 2012 and 2011, 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, 180,822 and 479,166 for the years ended December 31, 2013, 2012 and 2011, respectively. As of June 13, 2012 all of the deferred shares were expired. The total number of shares related to warrants excluded from the calculations of diluted net loss per share was 4,274,570 for the year ended December 31, 2013.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

k. 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.

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 2011, 2012 and 2013:

	December 31,		
	2013	2012	2011
Risk-free interest rate	0.45%-1.75%	0.69%-1.78%	0.34%-3.52%
Expected volatility	67.4%-85.55%	78.9%89.99%	51.1%-87.7%
Expected life (in years)	3.7-6.25	4.5-10.0	0.5-8.1
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 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 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The fair value of the ordinary shares underlying the options, warrants and deferred shares until December 31, 2011, had been determined by the Company's management, based on the share price used in the equity financing rounds. Since December 31, 2011 the Company issued shares and warrants to new investors (see also Note 9). In order to determine the fair value of the ordinary shares since December 31, 2011, management used the assistance of an independent valuation firm. The Company applied the market approach taking into account actual equity transactions. Since the equity transactions included warrant coverage, the Company isolated the value of the common share by subtracting the value of the warrants through performing a circular iteration in the Black Scholes option-pricing model. Because there has been no public market for the Company's ordinary shares, management has determined fair value of the ordinary shares at the time of grant of options by considering a number of objective and subjective factors, including valuation of warrants issued by the Company. The fair value of the underlying ordinary shares shall be determined by management until such time as the Company's ordinary share is traded on an established stock exchange or national market system.

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. Therefore, since the exercise price of some of the options, warrants and deferred shares is denominated in a currency that is different from the Company's functional currency, the Company accounts for such options and warrants as a liability.

1. Fair value of financial instruments:

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

The carrying amounts of cash and cash equivalents, 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:

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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.

m. 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"). As a result 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, 2013, 2012 and 2011, the Company recorded a net gain from derivatives transactions in the amount of \$ 270, \$ 419 and \$ 120, respectively.

n. Convertible notes:

The Company applies ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20"). In accordance with ASC 470-20, the Company first allocates 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 the Company's statement of comprehensive loss as financial income or expense. The remaining proceeds are allocated to the convertible note. The Company also recognized an embedded beneficial conversion feature on the commitment date. 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 convertible notes and warrants. The discount on the convertible notes is amortized according to the effective interest rate method over the life of the convertible notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 3:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2013	2012
Cost:		
Computers, peripheral and scientific equipment	\$ 9	\$ 12
Office furniture and equipment	1	1
	10	13
Accumulated depreciation:		
Computers, peripheral and scientific equipment	(9)	(10)
Office furniture and equipment	(1)	(1)
Depreciated cost	\$ -	\$ 2

Depreciation expense for the years ended December 31, 2013 and 2012 was \$ 2. In 2013 the Company disposed of property and equipment in amount of \$ 3.

NOTE 4:- ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2013	2012
Institutions	\$ 6	\$ 12
Prepaid expenses	169	2
	\$ 175	\$ 14

NOTE 5:- OTHER ACCOUNTS PAYABLE

	December 31,	
	2013	2012
Accrued expenses	\$ 403	\$ 896
Employees	176	359
	\$ 579	\$ 1,255

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6:- DEFERRED SHARES

- a. The holders of deferred shares shall not have any right other than the right to convert such shares into ordinary shares of £ 0.01 par value each upon the aforementioned events.
- b. In February 2005, the Company received a bridge loan from Capital Managers LLP ("CSS") (that was repaid in the course of 2005) in an amount of £ 200 thousand. In exchange for the loan, the Company issued to CSS 800,000 Ordinary shares of £ 0.01 par value each at a price of £ 1 per share and 400,000 Deferred A shares. The Deferred A shares entitle CSS the right to purchase 400,000 Ordinary shares, of £ 0.01 par value each, of the Company in one of the following: (i) during a period of 5 years, (ii) as part of a sale event involving the sale of all the Company's shares or (iii) upon the listing of the Company's shares for trade. The exercise price for a Deferred A share is £ 0.249.
- c. In February 2006, the Company issued 633,333 Deferred B shares of £ 0.001 par value each to CSS, for serving as broker for funds raisings. The Deferred B shares give CSS the right to purchase 633,333 Ordinary shares, of £ 0.01 par value each, of the Company in one of the following: (i) during a period of 5.25 years, (ii) as part of a sale event involving the sale of all the Company's shares or (iii) upon the listing of the Company's shares for trade. The exercise price for a Deferred B share is £ 0.59. As of December 31, 2011, the Deferred B shares have expired. The fair value of the Deferred B shares on the date of expiration in the amount of \$ 394 was recorded to additional paid-in capital.
- d. In June 2007, the Company issued 400,000 Deferred C shares of £ 0.001 par value each to Capital Management LLP ("CSS"), for serving as broker for fund raisings. The Deferred C shares entitle CSS the right to purchase 400,000 Ordinary shares, of £ 0.01 par value each, of the Company in one of the following: (i) during a period of 5 years, (ii) as part of a sale event involving the sale of all the Company's shares or (iii) upon the listing of the Company's shares for trade. The exercise price for a Deferred C share is £ 0.79.
- e. As part of the issuance of Deferred C Shares, the Company repurchased 400,000 Deferred A shares of £ 0.001 par value each that were issued in 2005. The Deferred A shares were acquired at par value.
- f. The Company accounted for the deferred shares in accordance with ASC 718 and ASC 505-50. Since the exercise price of such deferred shares was denominated in a currency that is different from the Company's functional currency, the Company accounted for such deferred shares as a liability. The fair value of the deferred shares was estimated each cut-off date using the Black-Scholes options valuation model. The changes in fair value were recorded as financial expense (income).
- g. During the years ended December 31, 2013, 2012 and 2011 the Company recorded financial income related to revaluation of deferred shares in the amount of \$ 0, \$ 88 and \$ 120.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6:- DEFERRED SHARES (Cont.)

- h. As of June 13, 2012, the Deferred C shares have expired. The fair value of the Deferred C shares on the date of expiration in the amount of \$ 128 was recorded to additional paid-in capital.

NOTE 7:- SHORT-TERM CONVERTIBLE NOTES

On April 4, 2012, the Company completed a private placement under a securities purchase agreement, dated April 3, 2012, by and among the Company and certain institutional accredited investors (the "April 2012 Financing"). As part of the April 2012 Financing, the Company sold an aggregate of \$ 1,100 principal amount of convertible notes (the "Notes") and warrants to purchase an aggregate of 643,274 ordinary shares (the "Warrants"), for a total consideration of \$ 1,000. The related issuance expenses were \$ 110. Each Note was convertible into shares at an initial conversion price of \$ 1.71 per ordinary share. On January 2, 2013, the Company repaid the Notes in the amount of \$ 1,100.

As part of the April 2012 Financing, the Company issued to the investors warrants (the "Warrants") to purchase an aggregate of 643,274 ordinary shares. The Warrants had an initial exercise price of \$ 1.71 per share, exercisable for a term of 5 years, subject to adjustment. The exercise price of the Warrants is subject to standard anti-dilution adjustments. In addition, the exercise price is also subject to "full ratchet" anti-dilution adjustment, similar to the Notes. To the extent the Company enters into a fundamental transaction (as defined in the Warrants and which includes, without limitation, entering into a merger or consolidation with another entity, selling all or substantially all of the assets, or a person acquiring 50% of the Company's voting shares), the holders will have the option to require the Company to repurchase the Warrants from the investor at its Black-Scholes fair value. Consequently, the Company accounts for the Warrants as a liability according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815"). In connection with the September 2013 Financing (as defined in Note 9b), the exercise price of the Warrants was reduced to \$ 0.57 and the number of Warrants was increased to 1,929,824 pursuant to the anti-dilution adjustments.

The Company applied ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20"). In accordance with ASC 470-20, the Company first allocated the proceeds received to the detachable warrants, a freestanding liability instrument that is measured at fair value at each reporting date, based on their fair value, with subsequent changes in the fair values being recognized in the Company's statement of comprehensive loss as financial income or expense. The fair value of Warrants granted was valued by using the Black-Scholes call option pricing model.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 7:- SHORT-TERM CONVERTIBLE NOTES (Cont.)

The anti-dilution rights of the Warrants were calculated by using Black-Scholes put option model using the same parameters as the warrants call option. Fair values were estimated using the following assumptions (annualized percentages):

	<u>December 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
Dividend yield	0%	0%
Expected volatility	84.09%	79.61%
Risk-free interest	0.16%	0.16%
Expected life	1.08 years	1.08 years
Forfeiture rate	0%	0%

The initial fair value of the detachable warrant on April 4, 2012 was \$ 750. On December 31, 2013 and 2012, the fair value of the detachable warrant was \$424 and \$ 402, respectively. The change in fair value in the amount of \$ 22 was recorded as financial income in the Company's statement of comprehensive loss.

The conversion feature in the Notes was not defined as a derivative instrument according to ASC 815, since the Company's shares were not traded on the commitment date. The Company recorded 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, the Company recorded a beneficial conversion feature, in accordance with Statement of Accounting Standard Codification No. 470-20, in the amount of \$ 250.

The discount on the Notes was amortized according to the effective interest rate method over the life of the Notes. During the year ended December 31, 2013, the Company recorded \$ 202 financial expenses in respect to the amortization of the discount of the Notes.

The issuance expenses that were allocated to the Warrants are recorded as financial expenses and the issuance expenses that were allocated to the Notes are capitalized and reported as deferred financing costs. The deferred financing cost is amortized over the life of the Notes using the effective interest rate. Since the issuance expenses that were allocated to the Notes were insignificant, all of the issuance expenses in the amount of \$ 110 were recorded as financial expenses.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 8:- 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 \$ 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.

b. Office lease commitment:

The Company's registered address is located in Great Britain with minimum rental commitments of \$ 0.6 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. The Company's liability as of December 31, 2013 is approximately \$ 2, to be paid during 2014.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY

- a. Composition of share capital:

	December 31, 2013		December 31, 2012	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
Ordinary shares of £ 0.01 par value each	49,800,000	40,227,953	49,800,000	13,369,809
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.

As for the deferred shares see Note 6.

- b. Shares and warrants issuances:

Since inception through December 31, 2010, the Company issued 11,561,571 ordinary shares of £ 0.01 par value each. The total proceeds amounted to \$ 7,587 (unaudited).

In the months January through September 2012, the Company issued 519,712 of ordinary shares, £ 0.01 par value each, at prices of \$ 1.72 - \$ 2.25 per share, for total gross proceeds of approximately \$ 944, net of \$ 75 included in receipt on the account of shares as of January 1, 2012. The investors were also granted with warrants to purchase 893,414 ordinary shares, at exercise prices of \$ 1.72 - \$ 2.25. In April 2012, the Company modified 39,500 warrants that were issued to investors in January 2012 with an exercise price of \$ 1 to a total of 79,000 warrants with an exercise price of \$ 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 deemed dividend in a total amount of \$ 33 to additional paid-in capital.

On November 30, 2012, the Company completed a private placement under the November Purchase Agreement (the "November Purchase Agreement"), by and among the Company and certain investors (the "November 2012 Financing"). As part of the November 2012 Financing, the Company sold an aggregate of 751,500 Ordinary Shares at \$ 2.00 per share for gross proceeds of \$ 1,503 and 375,750 warrants to purchase an aggregate of 375,750 Ordinary Shares at an initial exercise price of \$ 2.00 per share for a term of five years. The exercise price is subject to standard anti-dilution adjustments.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

In addition, under the terms of the November Purchase Agreement, from the date each investor entered into the November Purchase Agreement until (i) the two year anniversary of the effective date of a registration statement 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 November Purchase Agreement), 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").

On January 17, 2013, the Company issued 67,500 of ordinary shares, £ 0.01 par value each, at a price of \$ 2.00 per share, for total gross proceeds of \$ 135 that were paid in December 2012. The investors were also granted with warrants to purchase 33,750 ordinary shares, at an exercise price of \$ 2.00 and Most Favored Nation Terms.

On January 17, 2013, the Company completed a private placement, by and among the Company and certain investors (the "January 2013 Financing"). As part of the January 2013 Financing, the Company sold an aggregate of 405,500 ordinary shares at \$2.00 per share and 202,750 Series A warrants, 375,000 Series B warrants and 187,500 Series C warrants to purchase an aggregate of 765,250 ordinary shares (the "January 2013 Warrants"), for gross proceed of \$ 811.

Under the terms of the Agent Agreement (as defined in Note 9e5), the Company issued 43,035 Series A warrants with an exercise price of \$ 2.00 per share and a contractual life of five years. The fair value of the warrants at the commitment date was \$ 21. The Company also paid \$ 70 in cash, for advisory and legal services in relation with the January 2013 Financing.

The exercise price of the January 2013 Warrants is \$ 2.00. The Series A warrants and Series C warrants are exercisable for a term of five years and the Series B warrants are exercisable until April 2014. The vesting of the Series C warrants is dependent upon exercise of the Series B warrants. The Series C warrants shall become exercisable in proportion to the holder's exercise of the Series B warrant as compared with the total Series B warrants issued to such holder.

Under the January 2013 Financing, the Company also entered into a subsequent registration rights agreement with the investors pursuant to which the Company is required to file a registration statement to register the resale of up to 133% of the number of ordinary shares issued in the January 2013 Financing. The Company filed its registration statement on April 10, 2013 and it was declared effective by the SEC on April 16, 2013.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

Subject to certain limitations, the Series B warrants may be cancelled for consideration equal to \$ 0.001 per warrant share by the Company in the event that the closing sale price of the ordinary shares for each 20 consecutive trading days exceeds \$ 3.75 (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends, etc.) and (ii) the average daily volume for such 20 day period exceeds 75,000 ordinary shares or ADSs (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends, etc.).

The exercise price of the January 2013 Warrants is subject to standard anti-dilution adjustments. The investors were also granted Most Favored Nation Terms. In addition, while the January 2013 Warrants are outstanding if the Company will issue warrants at an effective price per share which is lower than the exercise price of the January 2013 Warrants, the exercise price of the January 2013 Warrants shall be reduced to the lower share price in the subsequent financing. In addition, until their expiry, the shares and the Series A warrants are also entitled to a price protection.

From January 31, 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 380,150 ordinary shares at \$ 2.00 per share and 190,075 Series A warrants, for gross proceeds of \$ 760. 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 9e5), the Company issued 10,800 warrants with an exercise price of \$ 2.00 per share and a contractual life of five years. The fair value of the warrants at the commitment date was \$ 5. The value of the warrants as of September 30, 2013 was \$ 4 and the change in value was recorded as financial expense.

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

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):

	December 31, 2013	December 31, 2012
Dividend yield	0%	0%
Expected volatility	85.45%	79.61%-86.31%
Risk-free interest	0.41%	0.12%-0.21%
Expected life	2.08 years	0.92-1.42 years

Fair values were estimated during 2013 and 2012 using the following assumptions for the warrants put option (range of annualized percentages):

	December 31, 2013	December 31, 2012
Dividend yield	0%	0%
Expected volatility	87.69%	67%-83%
Risk-free interest	0.21%	0.11%-0.28%
Expected life	1.33 years	0.25-1.04 years

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.

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 the warrants issued in the April 2012 purchase agreements with the Notes was reduced to \$ 0.57 per share, in accordance with the anti-dilution provisions contained in the April 2012 purchase agreements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

As of December 31, 2013 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) and 1,291,950 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).

c. Share option plan:

In August 2007, the Company adopted the share option plan (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. As of December 31, 2013, 1,608,310 ordinary shares are available for future issuance under the 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, 2012 and 2013:

	Amount of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2012	360,527	\$ 1.29		
Changes during 2012:				
Granted	410,000	\$ 1.58		
Options outstanding at December 31, 2012	770,527	\$ 1.44	7.2	\$ 169
Vested and expected to vest at December 31, 2012	770,527	\$ 1.44	7.2	\$ 169
Options exercisable at December 31, 2012	540,527	\$ 1.38	6.3	\$ 152
Outstanding at January 1, 2013	770,527	\$ 1.44	7.2	\$ 169
Changes during 2013:				
Granted	1,570,000	\$ 1.82		
Expired	(137,300)	\$ 1.51		
Options outstanding at December 31, 2013	<u>2,203,227</u>	<u>\$ 1.71</u>	<u>8.6</u>	<u>\$ -</u>
Vested and expected to vest at December 31, 2013	<u>2,203,227</u>	<u>\$ 1.71</u>	<u>8.6</u>	<u>\$ -</u>
Options exercisable at December 31, 2013	<u>633,227</u>	<u>\$ 1.44</u>	<u>5.9</u>	<u>\$ -</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's stock price on December 31, 2013 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.

During the year ended December 31, 2013, the Company recorded \$ 94 in share based compensation expenses. As of December 31, 2013, total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Company's stock option plans was \$ 362. That cost is expected to be recognized over a weighted-average period of 2.48 years.

- d. On January 18, 2005 and March 12, 2007, the chairman of the Company's board received warrants from the principle shareholder to purchase from it 50,700 and 152,000 Ordinary shares in consideration for par value of £ 0.01 and \$ 1.55 per share, respectively. The options were fully vested and valid for 10 years from grant date. The benefit in respect of the options totaling \$ 246 (unaudited) was included in the financial statements at grant date.

On March 1, 2011 the exercise price of 152,000 options granted on March 12, 2007 was adjusted to £ 0.01. The value of the benefit from the change in option terms (the difference between the options' value before the reduction in exercise price and the options' value after the reduction in exercise price) totaling \$ 95, was recorded as an expense in 2011. The options' fair value as of March 1, 2011 was determined based on \$ 1.63 share price, expected volatility of 86%, risk-free interest rate of 1.85%, expected dividend rate of 0%, and an expected life of 3 years.

- e. Options and warrants to service providers:

The options and warrants outstanding as of December 31, 2013 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 (3)	309,492	2.00	February 12, 2017
April 26, 2012 (2)	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
	543,135		

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

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 \$ 20 and \$ 3 for the years ended December 31, 2013 and 2012, respectively.

In 2012, the Company increased and changed the denominated currency of the exercise price of the options that were issued in 2009 from £ 0.8 to \$ 1.56 resulting in the options being reclassified from a liability to equity. The Company accounted for this change as a modification in accordance with ASC 718.

The Company calculated the incremental value of this modification. Since there was no incremental value, the Company only reclassified the related liability in the amount of \$ 35 to additional paid-in capital.

2. 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.

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

On February 29, 2012, the Company entered into an agreement with the Finder, for the purpose of introducing the Company to potential investors ("Finder's Agreement"). In the event that during the term of this agreement, an approved investor will consummate a cash investment, then the Finder shall be entitled to (i) a cash payment in an amount equal to 7% of the amount invested; and (ii) that number of ordinary shares of the Company issuable for a cash investment equal to 7% of the investment amount based upon the price per share pursuant to which the approved investor participated; less consulting consideration otherwise paid or payable to the Finder pursuant to a new consulting agreement that was signed in 2012 (the "2012 Consulting Agreement").

Between March through June 2012, the Company committed to grant an additional 20,000 fully vested warrants to the Finder under the 2012 Consulting Agreement (the "Finder's Warrants"). The exercise price was \$ 2 per share and the contractual life is five years. Pursuant to the terms of the Finder's Agreement, in September 2012, the Company issued, 16,279 ordinary shares, £ 0.01 par value each, and is obligated to pay \$ 28 in cash, in relation with the August 2012 financing (the "August Finder's Fee"), since the consulting fees pursuant to 2012 Consulting Agreement were lower than August Finder's Fee. The Company recorded an amount of \$ 52 of stock-based compensation expenses in the statement of comprehensive loss during the year ended December 31, 2012. After the August 2012 financing, the 2012 Consulting Agreement was terminated.

3. 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. See also Note 13.
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 November 2012 Financing.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9:- SHAREHOLDERS' EQUITY (Cont.)

f. Share-based payments:

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,		
	2013	2012	2011
Research and development	\$ (18)	\$ (2)	\$ -
General and administrative expenses	92	469	140
Financial (income), net		(82)	(120)
	\$ 74	\$ 385	\$ 20

NOTE 10:- 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 at 31 December 2013 is 23.25%, reduced from 24.5% from 1 April 2012. 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, 2013, the Company's net operating losses carryforward for tax purposes in Great Britain amounted to approximately \$ 9,400. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 10:- TAXES ON INCOME (Cont.)

The Subsidiary is subject to U.S. income taxes. As of December 31, 2013, the Subsidiary has net operating loss carry-forward for federal income tax purposes of approximately \$ 54 which expires in the years 2018-2029. The Subsidiary also has net operating loss carry-forward for 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.

e. 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.

NOTE 11:- FAIR VALUE MEASUREMENTS

In accordance with ASC No. 820, "Fair Value Measurements and Disclosures", the Company measures its liability related to stock based compensation 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 based compensation 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.

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 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 11:- FAIR VALUE MEASUREMENTS (Cont.)

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, 2013 and 2012, the fair value liability related to stock based compensation and warrants using input type Level 3 were \$ 787 and \$ 630, 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, 2011	\$	276
Changes in values of deferred shares and liability related to stock option and warrants		(418)
Expiration of deferred shares		(128)
Fair value of warrants at issuance date		1,076
Classification of liability award to equity as a result of expiration of the Most Favored Nation Terms (See Note 9b)		(141)
Classification of liability award to equity as a result of modification		(35)
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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 12:- 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 \$ 330 and \$ 718, respectively as of December 31, 2013 and 2012 and transactions with Service Provider charged to general and administrative expense were \$ 555, \$ 365 and \$ 413, respectively as of December 31, 2013, 2012 and 2011.

On February 12, 2012, \$ 309 out of the total outstanding balance owed to the Service Provider, who is also a related party, for services rendered until December 2011, was settled by the grant of fully vested warrants to purchase 309,492 ordinary shares, £ 0.01 par value each, of the Company at an exercise price of \$ 2 per share and a life of five years.

- b. On February 13, 2011, the members of the board of directors unconditionally waived any accrued and unpaid director's compensation (other than for rights granted in respect of options) as of that date. A related amount of \$ 73 was classified from other accounts payable to additional paid in capital.

In March 2012, the members of the board of directors unconditionally waived any director's cash compensation for their service from March 2012 and until the Company will receive an aggregate financing of at least \$ 15,000 in the private placement issuances from March 20, 2013 onward.

- c. According to an agreement signed in 2004, a retainer fee of £ 1.5 per quarter should be paid to one of the Company's former directors for financial advisory services (the "Advisory Agreement"). As of December 31, 2013 and 2012, the Company has an outstanding liability in the amount of \$ 0 and \$ 49, respectively for such services.

- d. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 13:- FINANCIAL EXPENSES (INCOME), NET

	Year ended December 31,		
	2013	2012	2011
Financial expenses:			
Interest expense due to amortization of convertible notes	\$ 202	\$ 898	\$ -
Issuance expenses	40	137	-
Exchange rate	35	-	-
Other	7	6	9
	<u>284</u>	<u>1,041</u>	<u>9</u>
Financial income:			
Changes in values of deferred shares and liability related to warrants	(270)	(418)	(120)
Exchange rate	-	(22)	(17)
	<u>(270)</u>	<u>(440)</u>	<u>(137)</u>
	<u>\$ 14</u>	<u>\$ 601</u>	<u>\$ (128)</u>

NOTE 14:- SUBSEQUENT EVENTS

- a. On February 5, 2014, Celsus Therapeutics Plc (the "Company") announced the closing of its public offering of 1,533,333 American Depository Shares ("ADSs") on the NASDAQ Capital Market at a price of \$ 6.00 per ADS. Each ADS represents 10 Ordinary Shares. The final number of ADSs includes the full exercise by the underwriter of its option to purchase 200,000 additional ADSs. Each ADS represents ten of the Company's ordinary shares. The gross proceeds from this offering, including from the exercise of the over-allotment option, before underwriting discounts and commissions and other offering expenses of approximately \$ 1,100, were approximately \$ 9,200. Celsus's ADSs are listed on the NASDAQ Capital Market under the trading symbol "CLTX" and began trading there on January 31, 2014. In connection with its listing on the NASDAQ Capital Market, the ADSs ceased trading on the OTCQB on January 30, 2014.
- b. On February 5, 2014, the Company granted 275,000 stock options to members of the board of directors at an exercise price of \$ 0.75 per share. In addition, the Company granted 300,000 stock options, to employees at an exercise price of \$ 0.75 per share. The options contractual term is 10 years and shall vest and become exercisable between May 31, 2014 and October 21, 2017.

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

I, Gur Roshwalb, certify that:

1. I have reviewed this annual report on Form 20-F of 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 company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 24, 2014

/s/ Gur Roshwalb

Gur Roshwalb, Chief Executive Officer

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

I, Dov Elefant, certify that:

1. I have reviewed this annual report on Form 20-F of 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 company as of, and for, the periods presented in this report;

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

- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

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

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

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

Date: March 24, 2014

/s/ Dov Elefant

Dov Elefant, Chief Financial Officer

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

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

- (i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2013 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 24, 2014

/s/ Gur Roshwalb

Gur Roshwalb

Chief Executive Officer

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

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

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

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2013 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 24, 2014

/s/ Dov Elefant

Dov Elefant

Chief Financial Officer

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