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

FORM 20-F

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

For the fiscal year ended December 31, 2013

Commission file number: 001-35932

Alcobra Ltd.
(Exact name of Registrant as specified in its charter)

State of Israel
(Jurisdiction of incorporation or organization)

Amot Investment Building
2 Weizman St. 9th Floor
Tel Aviv 6423902
(Address of principal executive offices)

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Tel: +972.72.220.4661
(Name, Telephone and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Name of each exchange on which registered
Ordinary Shares, par value of NIS 0.01	Nasdaq Capital Market

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

Indicate 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.

13,636,709 Ordinary Shares, par value NIS 0.01 per share

Indicate by check mark whether 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

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 Website, 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 (as defined in Rule 12b-2 of the Act).

☐ Large Accelerated Filer ☐ Accelerated Filer x 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

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INTRODUCTION

Unless otherwise indicated, all references to the "Company," "we," "our" and "Alcobra" refer to Alcobra Ltd. and its subsidiary, Alcobra Inc., a Delaware corporation. References to "U.S. dollars" and "$" are to currency of the United States of America, and references to "NIS" are to new Israeli shekels. References to "Ordinary Shares" are to our Ordinary Shares, par value of NIS 0.01 per share.

We do not endorse or adopt any third-party research or forecast firms' statements or reports referred to in this annual report and assume no responsibility for the contents or opinions represented in such statements or reports, nor for the updating of any information contained therein.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains express or implied "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws.

These forward-looking statements include, but are not limited to:

- Ÿ FDA approval of, or other regulatory action in the U.S. and elsewhere with respect to, MDX;
- Ÿ the commercial launch and future sales of MDX or any other future products or product candidates;
- Ÿ our ability to achieve favorable pricing for MDX;
- Ÿ designation of our drug candidate MDX as an orphan drug and implications if such designation is lost;
- Ÿ our expectations regarding the commercial supply of our MDX drug candidate;
- Ÿ third-party payor reimbursement for MDX;
- Ÿ our estimates regarding anticipated expenses, capital requirements and our needs for additional financing;
- Ÿ the Attention Deficit and Hyperactivity Disorder, or ADHD, patient market size and market adoption of MDX by physicians and patients;
- Ÿ the timing, cost or other aspects of the commercial launch of MDX;
- Ÿ the timing of commencement, duration and cost of clinical trials for MDX or whether such trials will be conducted at all;
- Ÿ completion and receiving favorable results of clinical trials for MDX;
- Ÿ issuance of patents to us by the United States Patent and Trademark Office, or U.S. PTO, and other governmental patent agencies;
- Ÿ the development and approval of the use of MDX for additional indications other than ADHD and Fragile X; and
- Ÿ our expectations regarding licensing, acquisitions and strategic operations.

In some cases, forward-looking statements are identified by terminology such as "may," "will," "could," "should," "expects," "plans," "anticipates," "believes," "intends," "estimates," "predicts," "potential," or "continue" or the negative of these terms or other comparable terminology. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or performance to differ materially from those projected. These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions or that historic results referred to in this press release would be interpreted differently in light of additional research and clinical and preclinical trials results. The forward-looking statements contained in this annual report are subject to risks and uncertainties, including those discussed under Item 3.D. – "Risk Factors" and in our other filings with the Securities and Exchange Commission, or the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to (and expressly disclaim any such obligation to) update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this annual report.

PART ONE

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. Selected financial data

Our historical consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States and are presented in U.S. dollars. The selected historical consolidated financial information as of December 31, 2012 and 2013 and for the years ended December 31, 2012 and 2013 have been derived from, and should be read in conjunction with, the consolidated financial statements of Alcobra Ltd. and notes thereto appearing elsewhere in this annual report. The selected financial data as of December 31, 2011 and for the year ended December 31, 2011 have been derived from the audited financial statements of Alcobra Ltd. not included in this annual report.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this annual report, and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion under Item 5 – "Operating and Financial Review and Prospects" - included elsewhere in this annual report.

Consolidated Statement of Operations Data – Year Ended December 31

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

	2013	2012	2011
Research and Development, net	$ 7,066	$ 818	$ 1,822
General and Administrative	3,224	683	2,084
Operating income	(10,290)	(1,501)	(3,906)
Financial expenses, net	197	78	23
Net income before taxes	(10,487)	(1,579)	(3,929)
Taxes on income (Tax benefit)	61	-	-
Deemed dividend	-	-	180
Net income	$ (10,548)	$ (1,579)	$ (4,109)
Basic net income and diluted net income per share	$ (1.04)	$ (0.20)	$ (0.50)
Shares used in computing basic and diluted net income per share	10,177,786	7,791,932	7,843,388

Consolidated Balance Sheet Data – Year Ended December 31

(in thousands of U.S. dollars, except for share data)

	2013	2012	2011
Working capital	$ 48,582	$ (588)	$ 448
Total assets	50,324	201	1,204
Shareholders' equity	$ 48,688	$ (567)	$ 985
Number of shares outstanding	13,636,709	7,794,256	8,096,109

3.B. Capitalization and indebtedness

Not applicable.

3.C. Reasons for the offer and use of proceeds

Not applicable.

3.D. Risk factors

In conducting our business, we face many risks that may interfere with our business objectives. Some of these risks could materially and adversely affect our business, financial condition and results of operations. In particular, we are subject to various risks resulting from changing economic, political, industry, business and financial conditions. The risks and uncertainties described below are not the only ones we face.

You should carefully consider the following factors and other information in this annual report before you decide to invest in our Ordinary Shares. If any of the negative events referred to below occur, our business, financial condition and results of operations could suffer. In any such case, the trading price of our Ordinary Shares could decline, and you may lose all or part of your investment.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend entirely on the success of our only current product candidate, MDX, and we may not obtain regulatory approval of MDX for the treatment of ADHD or other cognitive dysfunctions such as Fragile X, or we may be unable to successfully commercialize it.

We have invested almost all of our efforts and financial resources in the research and development of MDX, which is currently our only product candidate. As a result, our business is entirely dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize, MDX in a timely manner. The process to develop, obtain regulatory approval for, and commercialize MDX is long, complex, costly and uncertain of outcome.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drugs are subject to extensive regulation by the Food and Drug Administration, or FDA, in the United States and other regulatory agencies in other countries. These regulations differ from country to country. We are not permitted to market MDX or any other product candidate in the United States until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until we receive the requisite approval from regulatory agencies in such countries. We have not received regulatory clearance to conduct the additional clinical trials that are necessary to be able to submit an NDA to the FDA or comparable applications to other regulatory authorities in other countries or received marketing approval for MDX. The results of additional clinical trials may be unsatisfactory, and even if we believe those clinical trials to be successful, there are many reasons why the FDA may not approve our NDA should we be in a position to file one.

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 marketing 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. In particular, in many countries outside the United States, it is required that a product receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. In other countries, product approval depends on showing superiority to an approved alternative therapy. This can result in significant expense for conducting complex clinical trials. Finally, we do not have any products approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for MDX. This would reduce our target market and limit the full commercial potential of MDX.

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

We may not be able to commence or complete the clinical trials that would support our submission of an NDA to the FDA. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including:

- Ÿ difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- Ÿ delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Ÿ failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- Ÿ insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- Ÿ difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- Ÿ the FDA requiring alterations to any of our study designs, our pre-clinical strategy or our manufacturing plans;
- Ÿ challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- Ÿ difficulties in maintaining contact with subjects after treatment, which results in incomplete data;
- Ÿ receipt by a competitor of marketing approval for a product targeting an indication that our product targets, such that we are not “first to market” with our product candidate;
- Ÿ governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- Ÿ varying interpretations of data by the FDA and similar foreign regulatory agencies.

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 a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- Ÿ failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- Ÿ inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- Ÿ unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and

- Ÿ lack of adequate funding to continue the clinical trial.

Positive results in previous pre-clinical and clinical trials of MDX may not be replicated in future clinical trials of MDX, which could result in development delays or a failure to obtain marketing approval.

Positive results in previous pre-clinical and clinical studies of MDX may not be predictive of similar results in future clinical trials. Also, interim results during 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 the completed pre-clinical studies and clinical trials for MDX may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products.

Obtaining approval of an NDA even after clinical trials that are believed to be successful is an uncertain process.

Even if we complete our planned clinical trials and believe the results to be successful, all of which are uncertain, obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and the FDA (and other regulatory agencies) may delay, limit or deny approval of MDX for many reasons, including:

- Ÿ we may not be able to demonstrate to the satisfaction of the FDA that MDX is safe and effective for any indication;
- Ÿ the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval;
- Ÿ the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- Ÿ the FDA may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that MDX's clinical and other benefits outweigh its safety risks;
- Ÿ the FDA may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- Ÿ the FDA may not accept data generated at our clinical trial sites;
- Ÿ the data collected from pre-clinical studies and clinical trials of MDX may not be sufficient to support the submission of an NDA;
- Ÿ the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- Ÿ the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;
- Ÿ the FDA may identify deficiencies in the manufacturing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies;
- Ÿ the FDA may change its approval policies or adopt new regulations; and
- Ÿ the FDA may require simultaneous approval for both adults and for children and adolescents, delaying needed approvals, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Before we can submit an NDA to the FDA, we must conduct at least two clinical trials that will be substantially broader than our Phase 2 trial. Phase 3 clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, the results of the additional trials that we conduct may or may not be successful. The FDA may suspend all clinical trials or require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before it will consider or reconsider the NDA. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve the NDA. If any of these outcomes occur, we would not receive approval for MDX and may be forced to cease operations.

Even if we obtain FDA approval for MDX for the treatment of ADHD, or other cognitive dysfunctions, the approval might contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to significant post-marketing studies or risk mitigation requirements. If we are unable to successfully commercialize MDX, we may be forced to cease operations.

Even if MDX receives marketing approval, there could be adverse effects not discovered during development.

Even if MDX receives marketing approval, we or others may later identify undesirable side effects caused by the product or problems with our third-party manufacturers or manufacturing processes, and in either event a number of potentially significant negative consequences could result, including:

- Ÿ regulatory authorities may suspend or withdraw their approval of the product;
- Ÿ regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- Ÿ regulatory authorities may require us to issue specific communications to healthcare professionals, such as “Dear Doctor” letters;
- Ÿ regulatory authorities may issue negative publicity regarding the affected product, including safety communications;
- Ÿ we may be required to change the way the product is administered, conduct additional pre-clinical studies or clinical trials or restrict the distribution or use of the product;
- Ÿ we could be sued and held liable for harm caused to patients; and
- Ÿ our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase commercialization costs or even force us to cease operations.

We do not have significant pre-clinical or clinical data that support the applicability of MDX to other cognitive conditions, and ultimate regulatory approval for any additional applications is highly uncertain.

We recently completed two pre-clinical studies evaluating MDX in a recognized mouse model of Fragile X. In addition, we plan to investigate the use of MDX to treat other cognitive disorders and impairments. To date, we have obtained very little data regarding such uses. The regulatory approval process for additional indications may be as complex, time consuming and expensive as that for MDX in ADHD. As a result, ultimate regulatory approval for one or more of such indications is highly uncertain.

Obtaining regulatory approval for clinical trials of MDX in children will be more difficult than obtaining such approvals for adult clinical trials since the requirements for regulatory approval to conduct pediatric clinical trials are more stringent.

Pediatric drug development requires additional non-clinical work (such as animal studies in juvenile animals and additional reproductive toxicity work), as well as staged clinical work in determining safe dosing and monitoring. These additional tasks involve investment of significant additional resources beyond those needed for approval of the drug for adults. Approval of our drug for children may be significantly delayed due to these additional requirements.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of our clinical trials.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, as a result of which we may need to amend clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols to IRBs for review and approval, which may impact the cost, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for MDX would be harmed and our ability to generate product revenue would be delayed, possibly materially.

We may not be able to maintain FDA "Orphan Drug" designation for Metadoxine, the active ingredient in MDX to treat Fragile X. In addition, we might be prevented from commercializing such drug candidate if, for instance, another company receives marketing exclusivity for its drug candidate.

The regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Although we have obtained orphan drug designation for MDX to treat Fragile X in the United States, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize MDX or any other product candidate that we develop and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for MDX or any other product candidate that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell MDX or any other product candidate for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of MDX, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, was enacted. The PPACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. This law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of this law until applicable federal and state agencies issue regulations or guidance under it. The Centers for Medicare and Medicaid Services has proposed, but not yet promulgated, a regulation implementing aspects of the PPACA in the Medicaid drug rebate program. Although it is too early to determine its effect, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Even if MDX or any other product candidate that we develop receives marketing approval, we will continue to face extensive regulatory requirements and the product may still face future development and regulatory difficulties.

Even if marketing approval is obtained, a regulatory authority may still impose significant restrictions on a product’s indications, conditions for use, distribution or marketing or impose ongoing requirements for potentially costly post-market surveillance, post-approval studies or clinical trials. For example, any labeling ultimately approved by the FDA for MDX, if it is approved for marketing, may include restrictions on use, such as limitations on how ADHD is defined and diagnosed or limiting MDX to second-line or concomitant therapy. In addition, the labeling may include significant restrictions on use. MDX will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, distribution, promotion, recordkeeping and submission of safety and other post-market information, including adverse events, and any changes to the approved product, product labeling, or manufacturing process. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a drug. These risks include adverse drug interactions and concomitant therapy with other medications. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or cGMP, and other regulations.

If we, our drug products or the manufacturing facilities for our drug products fail to comply with applicable regulatory requirements, a regulatory agency may:

- Ÿ issue warning letters or untitled letters;
- Ÿ seek an injunction or impose civil or criminal penalties or monetary fines;

- Ÿ suspend or withdraw marketing approval;
- Ÿ suspend any ongoing clinical trials;
- Ÿ refuse to approve pending applications or supplements to applications;
- Ÿ suspend or impose restrictions on operations, including costly new manufacturing requirements;
- Ÿ seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or
- Ÿ refuse to allow us to enter into supply contracts, including government contracts.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

If we obtain approval to commercialize MDX outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If MDX is approved for commercialization outside the United States, we will likely enter into agreements with third parties to market MDX outside the United States. We expect that we will be subject to additional risks related to entering into or maintaining international business relationships, including:

- Ÿ different regulatory requirements for drug approvals in foreign countries;
- Ÿ differing United States and foreign drug import and export rules;
- Ÿ reduced protection for intellectual property rights in foreign countries;
- Ÿ unexpected changes in tariffs, trade barriers and regulatory requirements;
- Ÿ different reimbursement systems;
- Ÿ economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Ÿ compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- Ÿ foreign taxes, including withholding of payroll taxes;
- Ÿ foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- Ÿ workforce uncertainty in countries where labor unrest is more common than in the United States;
- Ÿ production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- Ÿ potential liability resulting from development work conducted by these distributors; and
- Ÿ business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from MDX. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

If we receive marketing approval for MDX, sales will be limited unless the product achieves broad market acceptance.

The commercial success of MDX and any other product candidate for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of the product by the medical community, including physicians, patients and healthcare payors. The degree of market acceptance of any approved product will depend on a number of factors, including:

- Ÿ demonstration of clinical safety and efficacy compared to other products;
- Ÿ the relative convenience and ease of administration;
- Ÿ the prevalence and severity of any adverse side effects;
- Ÿ limitations or warnings contained in the product's approved labeling;
- Ÿ distribution and use restrictions imposed by the FDA or agreed to by us as part of a mandatory or voluntary risk management plan;
- Ÿ availability of alternative treatments, including, in the case of MDX, a number of competitive products already approved for the treatment of ADHD (or Fragile X, or other cognitive dysfunctions, as the case may be) or expected to be commercially launched in the near future;
- Ÿ pricing and cost effectiveness;
- Ÿ the effectiveness of our or any future collaborators' sales and marketing strategies;
- Ÿ our ability to obtain sufficient third-party coverage or reimbursement; and
- Ÿ the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage.

If MDX is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate sufficient revenue from the product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of the product may require significant resources and may never be successful.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. In particular, any labeling approved by the FDA for MDX may include restrictions on use, such as limitations on how ADHD is defined and diagnosed or limiting MDX to second-line or concomitant therapy. The FDA may impose further requirements or restrictions on the distribution or use of MDX as part of a mandatory plan, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. If we receive marketing approval for MDX, physicians may nevertheless prescribe MDX to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

It will be difficult for us to profitably sell MDX if reimbursement for the product is limited.

Market acceptance and sales of MDX will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations (HMOs), decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for MDX and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. In addition, third-party payors are likely to impose strict requirements for reimbursement in order to limit off label use of a higher priced drug. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- Ÿ a covered benefit under its health plan;
- Ÿ safe, effective and medically necessary;
- Ÿ appropriate for the specific patient;
- Ÿ cost effective; and
- Ÿ neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost effectiveness data for the use of our product candidates to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidate. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before they can begin commercial manufacture of MDX, contract manufacturers must obtain regulatory approval of their manufacturing facilities, processes and quality systems. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections in a cost effective manner.

If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

We currently have no manufacturing, sales or distribution capabilities to market and sell MDX. If we do not establish these capabilities we will rely primarily on third parties to market and sell MDX.

We currently have no manufacturing, sales or distribution capabilities. To the extent we rely on third parties to commercialize MDX, if marketing approval is obtained, we may receive less revenue than if we commercialized MDX ourselves. In addition, we would have less control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to collaborate with a third-party marketing and sales organization to commercialize MDX, particularly for broader patient populations, our ability to generate revenue will be limited.

Our market is subject to intense competition. If we are unable to compete effectively, MDX or any other product candidate that we develop may be rendered noncompetitive or obsolete.

There are a number of existing treatments for ADHD currently on the market, all of which are marketed by pharmaceutical companies that are far larger and more experienced than we are. The FDA has not approved any drugs specifically for the treatment of Fragile X or its symptoms, although there are several pharmaceutical companies with compounds to treat Fragile X in late stage clinical development. Patients and doctors are often unwilling to change medications, and this factor will make it difficult for MDX to penetrate the market. Further, our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in, have engaged in or may engage in the future in the development, manufacturing, marketing and commercialization of new pharmaceuticals, some of which may compete with MDX or other product candidates we may have in the future. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. These companies may have products in development that are superior to MDX. Key competitive factors affecting the commercial success of MDX and any other product candidates that we may develop in the future are likely to be efficacy, time of onset, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Established competitors may invest heavily to quickly discover and develop novel compounds that could make MDX or other product candidates we may develop obsolete. Accordingly, our competitors may be more successful than we may be in obtaining FDA and other marketing approvals for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render MDX or any other product candidate that we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing the product. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render MDX or any other product candidate that we develop non-competitive or obsolete.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of MDX or other drugs exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare 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:

- Ÿ decreased demand for MDX or any other product candidate for which we obtain marketing approval;
- Ÿ impairment of our business reputation and exposure to adverse publicity;
- Ÿ increased warnings on product labels;
- Ÿ withdrawal of clinical trial participants;
- Ÿ costs of related litigation;
- Ÿ distraction of management's attention from our primary business;
- Ÿ substantial monetary awards to patients or other claimants;
- Ÿ loss of revenue; and
- Ÿ the inability to successfully commercialize MDX or any other product candidate for which we obtain marketing approval.

If product liability lawsuits are successfully brought against us, our insurance may be inadequate.

We have previously obtained clinical trial insurance coverage for our clinical trials with a $3.0 million annual aggregate coverage limit and we expect that we will obtain additional insurance as we conduct additional clinical trials. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, the insurance market experiences significant changes from year to year due to various factors including the international claims record and general reinsurance terms. Therefore, coverage may become more 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 MDX or any other product candidate, 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. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. 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.

The product liability insurance we will need to obtain in connection with the commercial sales of our product candidates if and when they receive regulatory approval may be unavailable in meaningful amounts or at a reasonable cost. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we would incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of our product programs.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.

We are an emerging biopharmaceutical company with a limited operating history. We are in the development stage. To date, we have focused almost exclusively on developing our lead compound, MDX. We have funded our operations to date primarily through proceeds from the private placement and public offering of ordinary shares and convertible notes. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. We have not generated any revenue from product sales to date. We have incurred losses in each year since our inception in February 2008. Our loss attributable to holders of our ordinary shares for the year ended December 31, 2012 and 2013 was approximately $1.6 million, and $10.5 million, respectively. As of December 31, 2013, we had an accumulated deficit of $18.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from general and administrative costs associated with our operations.

We expect our research and development expenses to increase in connection with our planned expanded clinical trials. In addition, if we obtain marketing approval for MDX, we will likely incur significant sales, marketing and outsourced manufacturing expenses, as well as continued research and development expenses. Furthermore, following the initial public offering of our ordinary shares in May 2013, we incur and expect to continue to incur additional costs associated with operating as a public company, which we estimate will be at least several hundred thousand dollars annually. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We have not generated any revenue from MDX or any other product candidate and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage product candidate, MDX, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue from sales of our product candidate unless or until we obtain marketing approval of, and commercialize, MDX. Our ability to generate revenue depends on a number of factors, including our ability to:

- Ÿ obtain favorable results from and progress the clinical development of MDX;
- Ÿ develop and obtain regulatory approval for registration studies protocols for MDX;
- Ÿ subject to successful completion of registration, clinical trials and perhaps additional clinical trials of MDX, apply for and obtain marketing approval;
- Ÿ contract for the manufacture of commercial quantities of MDX at acceptable cost levels if marketing approval is received; and
- Ÿ establish sales and marketing capabilities, both internal and external, to effectively market and sell MDX in the United States and other countries.

Even if MDX is approved for commercial sale for the treatment of ADHD or Fragile X, it may not gain market acceptance or achieve commercial success. In addition, we anticipate incurring significant costs associated with commercialization. We may not achieve profitability soon after generating product revenue, if ever. If we are unable to generate product revenue, we will not become profitable and would be unable to continue operations without continued funding.

We may need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We may need to raise substantial additional capital to fund our operations and to develop and commercialize MDX. Our future capital requirements may be substantial and will depend on many factors including:

- Ÿ our clinical trials results;
- Ÿ the scope, progress, results and costs of researching and developing MDX;
- Ÿ the cost, timing and outcomes of seeking marketing approval of MDX;
- Ÿ the cost of filing and prosecuting patent applications and the cost of defending our one issued patent and future patents, if issued;
- Ÿ the cost of prosecuting infringement actions against third parties;
- Ÿ exploration and possible label expansion of MDX for the treatment of other conditions;
- Ÿ the costs associated with commercializing MDX if we receive marketing approval, including the cost and timing of establishing sales, marketing and distribution capabilities to market and sell MDX;
- Ÿ the cost of manufacturing MDX;
- Ÿ the timing, receipt and amount of sales of, or royalties on, sales of MDX, if any;
- Ÿ subject to receipt of marketing approval, revenue received from sales of approved products, if any, in the future;
- Ÿ any product liability or other lawsuits related to our products;
- Ÿ the expenses needed to attract and retain skilled personnel; and
- Ÿ the costs associated with being a public company.

Based on our current operating plan, we anticipate that our existing resources will be sufficient to enable us to maintain our currently planned operations, including our continued product development (which does not include conducting clinical trials in the EU or Japan), at least through 2016. We believe these funds will enable us, among other things, to complete any preparatory clinical and non-clinical work, as well as two Phase 3 clinical trials in ADHD for adults, complete two advanced clinical trials of MDX for Fragile X and to complete the necessary preparations and conducting a Phase 3 clinical study in children that suffer from ADHD. We will require significant additional funds to initiate and complete the FDA approval process. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate. We have no committed external sources of funds. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

- Ÿ delay, limit, reduce, or terminate clinical trials or other development activities for MDX; or

- Ÿ delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize MDX, if we obtain marketing approval.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible notes securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to Our Reliance on Third Parties

We have no manufacturing capacity and may choose to rely on third-party manufacturers for our products.

We do not currently operate manufacturing facilities for clinical production of MDX. We do not intend to develop facilities for the manufacture of products for clinical trials or commercial purposes in the foreseeable future. We will rely on third-party manufacturers to produce bulk drug products required for our clinical trials on a timely basis. We plan to continue to rely upon CMOs and, potentially, collaboration partners to manufacture commercial quantities of our drug product candidates if and when approved for marketing by the applicable regulatory authorities. If the third-party manufacturing sources we rely on cease to be available to us on commercially reasonable terms or on a timely basis, we may not be able to complete development, production and marketing of MDX.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. We will be dependent on the ability of these third-party manufacturers to produce supplies of drug product adequate to support our clinical development programs and future commercialization of our MDX. In addition, the FDA and other regulatory authorities require that MDX be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of MDX in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of MDX. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We have limited staffing and rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce MDX for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we use to manufacture our drugs. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate or the material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for MDX, its commercial launch would be delayed or there would be a shortage in supply, either of which would impair our ability to generate revenues from the sale of MDX.

Our contract manufacturers have not completed process validation for the drug substance manufacturing process. If our contract manufacturers are not approved by the FDA, our commercial supply of drug substance will be significantly delayed and may result in significant additional costs. We purchase finished MDX drug product from a third party under a clinical supply agreement. We do not have an agreement in place for, and we have not identified, a secondary fill/finish supplier. If we need to identify an additional fill/finish manufacturer, we would not be able to do so without significant delay and likely significant additional cost.

Our contract manufacturer's failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Our existing manufacturers and any future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of MDX would be interrupted, resulting in delays and additional costs.

In addition, because our contract manufacturers of the bulk drug substance are located outside of the United States, we may face difficulties in importing our drug substances into the United States as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and potential future product candidates. We may enter into these arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with other pharmaceutical or biotechnology companies for each product candidate, both in the United States and internationally. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on acceptable terms or at all.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We currently depend on third parties to conduct our clinical trials.

We rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to oversee some of the operations of our clinical trials and to perform data collection and analysis. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such agreement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. Even if we are able to maintain or enter into such agreements, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion or in accordance with regulatory requirements. If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our financial results and the commercial prospects for MDX or any other potential product candidates could be harmed, our costs could increase and our ability to obtain regulatory approval and commence product sales could be delayed.

Risks Related to Our Intellectual Property

We have filed multiple patent applications and have one issued patent by the U.S. PTO. There can be no assurance that any of our other patent applications will result in issued patents. As a result, we may have limited protection of our proprietary technology in the marketplace.

We have filed patent applications in many countries worldwide. These applications cover a range of areas including: different formulations of Metadoxine, the use of Metadoxine for all cognitive impairments, combination therapy including Metadoxine, new molecular derivatives of Metadoxine and the manufacturing and production of Metadoxine API. The U.S. PTO has issued one patent to us, covering the composition of the sustained release form of MDX. Unless and until other pending applications issue, their additional protective scope is impossible to determine. It is impossible to predict whether or how many of these additional applications will result in issued patents. Even if pending applications issue, they may issue with claims significantly narrower than those we currently seek. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the U.S. PTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology.

The patent positions of pharmaceutical products are complex and uncertain and therefore we cannot predict the scope and extent of patent protection for MDX with respect to our issued patent, or any patents we may be issued in the future.

The patent we were issued as well as any additional patents that may in the future issue to us will not ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- Ÿ any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
- Ÿ if we are not issued additional patents or if issued patents expire, there would be no protections against competitors making generic equivalents;
- Ÿ there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- Ÿ there may be other patents existing in the patent landscape for MDX that will affect our freedom to operate;
- Ÿ if our one issued patent or future ones, if issued, are challenged, a court could determine that they are not valid or enforceable;
- Ÿ a court could determine that a competitor's technology or product does not infringe our one issued patent or future patents, if issued;
- Ÿ our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- Ÿ our one issued patent and future patents, if issued, could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- Ÿ if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

We may not be able to enforce our intellectual property rights throughout the world. This risk is exacerbated for us because Metadoxine is manufactured and used in a number of foreign countries in other applications.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us because Metadoxine is manufactured and used in a number of foreign countries in other applications and is widely available. The manufacture of Metadoxine and its use in other indications will not infringe our intellectual property rights, and will make it more difficult to monitor and enforce any patent rights that may be issued to us.

The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of any in-licensed patents we may acquire or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes.

Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we obtained a license under the applicable patents, or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we or any future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing one or more of our products or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

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

We rely on trade secrets to protect our proprietary know-how and technological advances, 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. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us.

We generally enter into non-competition agreements with our employees and certain key consultants. These agreements prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished. In addition, the Israeli Supreme Court ruled in 2012 that an employee who receives a patent or contributes to an invention during his employment may be allowed to seek compensation for it from their employer, even if the employee’s contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Supreme Court ruled that the fact that a contract revokes the employee’s right for royalties and compensation, does not rule out the right of the employee to claim their right for royalties. As a result, it is unclear if, and to what extent, our employees may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if such claims are successful which in turn could impact our future profitability.

Any lawsuits relating to infringement of intellectual property rights necessary to defend ourselves or enforce our rights will be costly and time consuming.

Our ability to defend our intellectual property may require us to initiate litigation to enforce our rights or defend our activities in response to alleged infringement of a third party. In addition, we may be sued by others who hold intellectual property rights who claim that their issued patents are infringed by MDX or any future products or product candidates. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally.

In addition, our patent and patent applications, or those of our licensors, could face other challenges, such as interference proceedings, opposition proceedings, and re-examination proceedings. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patent and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management's time and attention.

Changes in U.S. patent law could diminish the value of our one issued patent, or future patents, if issued, in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our ordinary shares to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs or intellectual property could be diminished. Accordingly, the market price of our ordinary shares may decline.

Risks Related to Our Business Operations and Industry

We are a clinical-stage company with no approved products, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- Ÿ execute product candidate development activities;
- Ÿ obtain required regulatory approvals for the development and commercialization of our product candidates;
- Ÿ maintain, leverage and expand our intellectual property portfolio;
- Ÿ build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- Ÿ gain market acceptance for our products;
- Ÿ develop and maintain any strategic relationships we elect to enter into; and
- Ÿ manage our spending as costs and expenses increase due to drug discovery, pre-clinical development, clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

We manage our business through a small number of employees and key consultants. We depend on them even more than similarly-situated companies.

Our key employees include our Chief Executive Officer, Dr. Yaron Daniely, who has been with us since 2010, our Chief Medical Officer, Dr. Jonathan Rubin, who has been with us since 2013, our Chief Commercial Officer, Mr. David Baker, who has been with us since 2014, our Senior Vice President CMC (chemistry, manufacturing and controls), Ms. Hanna Ron, who has been with us since 2011, our Vice President, Finance, Mr. Nir Peles, who has been with us since 2013, and our Vice President of Preclinical Development, Dr. Johanna Schumann, who has been with us since 2013. A key consultant is our Chief Financial Officer/Chief Accounting Officer, Mr. Udi Gilboa, who co-founded us in 2008 and has been with us since such time. We recently announced that Dr. Tomer Berkovitz will assume the role of the Company's Chief Financial Officer and that Mr. Gilboa will step down from this position. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees and key consultants. The loss of the services of our chief executive officer, our new chief financial officer or any of our key employees or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Although we have employment agreements in place with management, these agreements are terminable at will with minimal notice.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific and technical consultants. In particular, the loss of one or more of our senior executive officers or key consultants could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not currently carry “key person” insurance on the lives of members of senior management. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, our shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

We are required to disclose changes made in our internal controls and procedures on an annual basis and beginning with our next annual report our management will be required to assess the effectiveness of these internal controls annually. However, for as long as we are an "emerging growth company" under the Jump Start our Business Startups Act of 2012, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We may need to significantly increase the size of our organization, and we may experience difficulties in managing growth.

We currently have only 9 employees and plan to recruit up to 3 more in the near future, and in order to commercialize our products, we may need to substantially increase our operations, including expanding our employee base of managerial, operational and financial personnel. Any future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To that end, we must be able to:

Ÿ manage our clinical trials and the regulatory process effectively;

Ÿ hire and train additional qualified personnel; and

Ÿ integrate current and additional management, administrative, financial and sales and marketing personnel.

Our relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, or the Anti-Kickback Statute, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by health care providers, health plans and health care clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures; and

- analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries may also apply.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. Despite the adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee from trading in our ordinary shares on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

Our business may be affected by macroeconomic conditions.

A deterioration in global economic conditions and uncertainties may have an adverse effect on our business. Interest rates and the ability to access credit markets could adversely affect the ability of patients and distributors to purchase, pay for and effectively distribute our products. Similarly, these macroeconomic factors could affect the ability of our CMOs, sole-source or single-source suppliers to remain in business or otherwise manufacture or supply product. Failure by any of them to remain a going concern could affect our ability to manufacture products.

Risks Related to Our Ordinary Shares

We do not know whether a market for our ordinary shares will be sustained or what the market price of our ordinary shares will be and as a result it may cult for you to sell your shares.

Although our ordinary shares are quoted on the NASDAQ Capital Market, an active trading market for our shares may not be sustained. It may be difficult for you to sell your shares at all or without depressing the market price for the shares. As a result of these and other factors, you may not be able to sell your ordinary shares at or above the price you paid for such shares or at all. In addition, the trading price of our ordinary shares is likely to be volatile. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our ordinary shares:

- Ÿ inability to obtain the approvals necessary to commence further clinical trials;
- Ÿ unsatisfactory results of clinical trials;
- Ÿ announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- Ÿ announcements of therapeutic innovations or new products by us or our competitors;
- Ÿ adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- Ÿ changes or developments in laws or regulations applicable to MDX;
- Ÿ any adverse changes to our relationship with manufacturers or suppliers;
- Ÿ any intellectual property infringement actions in which we may become involved;
- Ÿ announcements concerning our competitors or the pharmaceutical industry in general;
- Ÿ achievement of expected product sales and profitability or our failure to meet expectations;
- Ÿ our commencement of, or involvement in, litigation;
- Ÿ any major changes in our Board of Directors or management;
- Ÿ legislation in the United States relating to the sale or pricing of pharmaceuticals; or
- Ÿ future substantial sales of our ordinary shares.

In addition, the stock market in general, and NASDAQ Stock Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our two major shareholders currently own approximately 42% of our outstanding ordinary shares. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

Our two major shareholders, in the aggregate, beneficially own approximately 42% of our ordinary shares. This significant concentration of share ownership may adversely affect the trading price for our ordinary shares because investors often perceive disadvantages in owning stock in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders.

Sales of a substantial number of our ordinary shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of our ordinary shares in the public market or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ordinary shares.

If we were to be characterized as a "passive foreign investment company" for U.S. tax purposes, U.S. holders of our ordinary shares could have adverse U.S. income tax consequences.

If we were to be characterized as a passive foreign investment company, or PFIC, under the U.S. Internal Revenue Code of 1986, as amended, or the Code, in any taxable year during which a U.S. taxpayer owns ordinary shares, such U.S. holder could be liable for additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition, including a pledge, of the ordinary shares, whether or not we continue to be a PFIC. See "U.S. Federal Income Tax Consequences."

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could decline.

The trading market for our ordinary shares will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Because we do not intend to declare cash dividends on our ordinary shares in the foreseeable future, shareholders must rely on appreciation of the value of our ordinary shares for any return on their investment.

We have never declared or paid cash dividends on our ordinary shares. 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 in the foreseeable future. Moreover, the Israeli Companies Law imposes certain restrictions on our ability to declare and pay dividends. See "Description of Share Capital—Dividend and Liquidation Rights" for additional information.

The requirements associated with being a public company require significant company resources and management attention.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, listing requirements and other applicable securities rules and regulations. The Exchange Act requires that we file periodic reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and the NASDAQ Stock Market may also impose various additional requirements on public companies. As a result, we incur additional legal, accounting and other expenses that we did not incur as a nonpublic company. We estimate that these expenses will be at least several hundred thousand dollars annually. We made changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. The measures we take, however, may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our ordinary shares, fines, sanctions and other regulatory action and potentially civil litigation.

The JOBS Act will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our ordinary shares.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies" including:

- Ÿ the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- Ÿ our ability not to comply with new accounting principles that do not apply to public companies until such accounting principles become applicable to private companies; and

- Ÿ any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our ordinary shares less attractive because we may 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 ordinary shares, and our share price may be more volatile and may decline.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and NASDAQ requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the NASDAQ Stock Market for domestic U.S. issuers. For instance, we intend to follow home country practice in Israel with regard to, among other things, director nomination procedures and approval of compensation of officers. In addition, we may follow our home country law instead of the Listing Rules of the NASDAQ Stock Market that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on NASDAQ may provide less protection to you than what is accorded to investors under the Listing Rules of the NASDAQ Stock Market applicable to domestic U.S. issuers.

In addition, as a foreign private issuer, we are exempt from the rules and regulations 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 domestic U.S. issuers whose securities are registered under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you are entitled as an investor.

Risks Related to Israeli Law and Our Operations in Israel

Our headquarters and other significant operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

Our executive offices are located in Tel Aviv, Israel. In addition, the majority of our officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Since March 2011, there has been a civil war in Syria, Israel's neighboring country to the north. Occasionally, violence from Syria has spilled over into Israel's border, and Israel has responded militarily several times since the onset of the civil war. During November 2012, Israel was engaged in an armed conflict with a militia group and political party which controls the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may sometimes decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is has in the past covered the reinstatement value of certain damages that were caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial conditions or the expansion of our business.

Our operations may be disrupted as a result of the obligation of management or key personnel or consultants to perform military service.

Our male employees and consultants in Israel, including members of our senior management, may be obligated to perform one month, and in some cases longer periods, of annual military reserve duty until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves). In this connection, we note that our chief executive officer, Yaron Daniely, is 38 years old. In the event of a military conflict, he and other of our key personnel or consultants may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our officers, directors, employees and consultants. Such disruption could materially adversely affect our business and operations.

Exchange rate fluctuations between the U.S. dollar and the New Israeli Shekel currencies may increase our expenses.

The vast majority of our expenses are in U.S. dollars and New Israeli Shekels, or NIS. Our functional currency is the U.S. dollar and substantially all of our financial resources are denominated by U.S. dollars. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the U.S. dollar cost of our operations in Israel would increase and our U.S. dollar-denominated results of operations would be adversely affected. For instance, in 2013, approximately 12% of our expenses were denominated in New Israeli Shekel. Changes of 5% and 10% in the U.S. dollar - NIS exchange rate would have increased/decreased the operation expenses by 2% and 4%, respectively. The exchange rate as of December 31, 2013 was $1.00 = NIS 3.471. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

In the past, we received Israeli government grants for certain of our research and development activities. The terms of those grants may require us, in addition to payment of royalties, to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.

Our research and development efforts, during the period between May 1, 2009 and April 30, 2010, were financed in part through royalty-bearing grants, in an amount of $106,494 that we received from Israel's Office of the Chief Scientist of the Ministry of Industry, Trade and Labor, or OCS. With respect to such grants we are committed to pay royalties at a rate of 3% to 5% on sales proceeds from MDX, according to the OCS approval, the company is required to pay royalties from any income generated in connection with delayed release Metadoxine tablets up to the total amount of grants received, linked to the U.S. dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. Regardless of any royalty payment, we are further required to comply with the requirements of the Israeli Encouragement of Industrial Research and Development Law, 5744-1984, and related regulations, or the Research Law, with respect to those past grants. When a company develops know-how, technology or products using OCS grants, the terms of these grants and the Research Law restrict the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the OCS. Therefore, if aspects of our technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies, and may result in payment of increased royalties (both increased royalty rates and increased royalties ceilings) and/or payment of additional amounts to the OCS. We may not receive those approvals. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel (including for the purpose of manufacturing). Currently, under the Research Law, there is no mechanism for the approval of licensing transactions of OCS-supported technologies, however, licensing OCS supported technologies may under certain circumstances be considered a transfer of know-how and therefore requires approval as aforementioned.

The transfer of OCS-supported technology or know-how outside of Israel may involve the payment of additional amounts depending upon the value of the transferred technology or know-how, the amount of OCS support, the time of completion of the OCS-supported research project and other factors up to a maximum of six times the amount of grants received. These restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel (particularly since currently there is no mechanism for the approval of licensing transactions of OCS supported technologies). Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with OCS funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the OCS.

Our obligations and limitations pursuant to the Research Law are not limited in time and may not be terminated by us at will. As of the date hereof, we have not been required to pay any royalties with respect to the OCS grants. As of the date hereof, production of bulk drug substance and drug products required for our clinical trials does not involve manufacture of OCS supported products, technologies or know-how, and/or transfer of OCS supported technologies or know-how, and therefore no OCS committee approval has been sought after or required in connection with such production by our third-party manufacturer, Patheon Inc., located in Cincinnati, Ohio.

Provisions of Israeli law and our amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the Company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. See “Taxation—Israeli Tax Considerations” for additional information.

Our amended and restated articles of association also contain provisions that could delay or prevent changes in control or changes in our management without the consent of our Board of Directors. These provisions include the following:

- no cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates; and

- the right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which may prevent shareholders from being able to fill vacancies on our Board of Directors.

It may be difficult to enforce a judgment of a United States court against us and our officers and directors and the Israeli experts named herein in Israel or the United States, to assert United States securities laws claims in Israel or to serve process on our officers and directors and these experts.

We were incorporated in Israel. The vast majority of our executive officers and directors reside outside of the United States, and all of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not necessarily be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to United States securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of United States securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a United States or foreign court.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has certain duties to act in good faith and fairness towards the Company and other shareholders, and to refrain from abusing its power in the Company. See Item 7 – "Major Shareholders and Related Party Transactions" for additional information. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

It may be difficult to effect service of process and enforce judgments against directors, officers and experts in Israel.

We are incorporated and maintain significant operations in Israel. Some of our executive officers and directors and the Israeli accountants named in this annual report reside outside the United States and a significant portion of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to affect service of process on us or any of those persons or to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws, against us or any of those persons, in an Israeli court. Additionally, it may be difficult for an investor or any other person or entity to enforce civil liabilities under U.S. federal securities laws in original actions instituted in Israel.

We are subject to anti-takeover provisions that could delay or prevent our acquisition by another entity.

Provisions of Israeli corporate and tax law and of our articles of association may have the effect of delaying, preventing or making more difficult any merger or acquisition of us. In addition, any merger or acquisition of us will require the prior consent of the office of the chief scientist, or the Chief Scientist, if intellectual property is removed from Israel, as well as the Investment Center of the Israeli Ministry of Industry, Trade and Employment, or the Investment Center. Israeli law regulates mergers, votes required to approve a merger, acquisition of shares through tender offers and transactions involving significant shareholders. In addition, our articles of association provide for a staggered board of directors. Any of these provisions may make it more difficult to acquire us. Accordingly, our acquisition by another entity could be delayed or prevented even if it would be beneficial to our shareholders.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and development

We are an Israeli corporation based in Tel Aviv and were incorporated in 2008. Our principal executive offices are located at Amot Investment Building, 2 Weizman St. 9th Floor, Tel Aviv 6423902 Israel, and our telephone number is +972 72 220 4661. Our website address is www.alcobra-pharma.com. The information contained on, or that can be accessed through, our website is not part of this form. We have included our website address herein solely as an inactive textual reference.

We are an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not “emerging growth companies” such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We could remain an “emerging growth company” for up to five years, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1 billion, (b) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1 billion in nonconvertible debt during the preceding three-year period. Our wholly owned U.S. subsidiary, Alcobra, Inc., has been appointed our agent in the United States and is located at 600 West Germantown Pike, Suite 400, Plymouth Meeting, PA, 19462.

Our capital expenditures for 2013, 2012, and 2011 amounted to $39,000, $0, and $24,000, respectively. These expenditures were primarily for computers, other electrical equipment and office furniture. Our current capital expenditures are primarily for leasehold improvements, computers and other electronic equipment, and we expect to finance these expenditures primarily from cash on hand.

4.B. Business overview

Who We Are

We are an emerging biopharmaceutical company primarily focused on the development and commercialization of our proprietary oral drug candidate, MDX, to treat ADHD and other cognitive dysfunctions including Fragile X Syndrome. The most common currently available treatments for ADHD are stimulants that increase the brain chemicals dopamine and norepinephrine. Stimulants have significant side effects, and are classified as controlled substances which have significant potential for misuse, abuse and addiction. MDX is not a stimulant, and works with a different mechanism of action. MDX is a proprietary, combined rapid onset/extended release formulation of the chemical Pyridoxine Pyroglutamate, which is more broadly known as Metadoxine. Metadoxine has been available since the 1980s only in immediate release forms for the acute treatment of alcohol intoxication and the chronic treatment of alcoholic liver disease in Italy, Portugal, Hungary, Russia, India, China, Mexico and Thailand. In September 2011, we completed a 120 subject double-blind placebo-controlled Phase 2 study in adult ADHD subjects in Israel that showed statistically significant improvement in clinical ADHD symptoms, and also showed favorable tolerability with no significant side effects over a placebo. The trial met all primary and secondary clinical endpoints showing statistically significant improvement over the placebo-treated control group. In December 2013, we completed an additional 36 subject double-blind placebo-controlled Phase 2 study in adult ADHD confirming our previous findings and highlighting the rapid onset of the drug, demonstrating efficacy over placebo from first day of dosing.

We have initiated a Phase 3 clinical trial in the United States for the use of MDX to treat ADHD in adults. If this and any future clinical trials demonstrate the safety and efficacy of MDX, we will seek to obtain marketing approval from the FDA for MDX for use in adults. We have similar plans to seek marketing approval in the European Union, Japan and other territories.

Subject to obtaining the necessary regulatory clearances, we further plan to conduct a Phase II study in pediatric ADHD in 2014, followed by a Phase 3 study in this population in 2015, and, if the data supports it, proceed to request a marketing authorization. The requirements to conduct pediatric clinical trials are more stringent than those for adults.

ADHD is one of the most common behavioral disorders in the world. It is estimated that between 8% and 10% of children worldwide are affected by this condition. Once believed to only affect children, ADHD is now known to persist into adolescence and adulthood in a large number of cases, with approximately 50% of all adults who had ADHD as children continuing to have symptoms of the disorder as adults. Over 90% of these adults experience impaired attention and executive function symptoms, of which approximately 35% also experience hyperactivity-impulsivity symptoms.

ADHD is a treatable condition. The most commonly used therapeutic drugs are stimulants (Schedule II, Controlled Substances), such as Ritalin, Adderall, Vyvanse and Concerta, which are all dopaminergic (related to dopamine) and noradrenergic (related to norepinephrine) compounds with significant abuse and misuse potential because their use may lead to severe psychological or physical dependence. In addition, stimulants have numerous side effects, such as uncomfortable mental states, interference with sleep and appetite, development of nervous tics and potential cardiovascular effects resulting from increased blood pressure and heart rate. These side effects have limited effective treatment in those taking the drugs and have also dramatically limited medication adherence rates. Up to 30% to 50% of those who are prescribed stimulants for ADHD either do not respond or cannot tolerate these treatments, and only about 20% of those who are prescribed stimulants are still taking them 12 months later. There also is a non-stimulant drug approved for children and adults with ADHD called Strattera (Atomoxetine), approved in 2002. This drug also has significant side effects, such as fatigue, gastrointestinal, or GI, upset, sexual problems, palpitations, increased heart rate and high blood pressure and also has regulatory warning labels relating to suicidal thoughts and liver damage. Moreover, Strattera takes six to 10 weeks to achieve full clinical effectiveness. More recently, two additional non-stimulant medications were approved for use only in children and adolescents with ADHD (Intuniv (Guanfacine) and Kapvay (Clonidine)). These two drugs have not been approved for use in adults with ADHD and have not had significant commercial success. All approved ADHD drugs need to be carefully monitored by the treating physician to optimize the dose, starting with a low dose and slowly escalating to the most effective and tolerable dose.

In contrast to the most common available treatments which involve the use of stimulants, MDX is not a stimulant with a differentiated mechanism of action that is neither dopaminergic (related to dopamine) nor noradrenergic (related to norepinephrine). Our 120 subject Phase 2 study showed significant improvement in clinical symptoms with higher response rates, and a more rapid onset than available non-stimulants, confirmed by our second 36 subject Phase 2 study. Both trials also demonstrated favorable tolerability and safety. MDX therefore potentially represents a safer alternative to stimulant-based treatments and a more tolerable and effective treatment than the non-stimulants which are currently in the market.

In addition, because of its unique mechanism of action and specific clinical effect on inattention and cognitive function, we believe that MDX possibly may be useful in treating additional cognitive disorders. Accordingly, we completed pre-clinical studies evaluating metadoxine in the standard mouse model of Fragile X Syndrome (Fmr1 knockout mouse). The studies showed significant improvement in cognitive and social functioning following treatment with metadoxine in the Fragile X mouse model.

Fragile X Syndrome, a rare disease, as defined by the Orphan Drug Act, is the most common single-gene cause of autism and inherited cause of intellectual disability among boys. Approximately one in 4,000 males and one in 8,000 females have Fragile X, according to Centers for Disease Control and Prevention (CDC). Not everyone with the mutation will show signs or symptoms of Fragile X, and disabilities will range from mild to severe and may include physical characteristics such as an elongated face, large or protruding ears and large testes , and behavioral characteristics such as stereotypic movements (e.g. hand-flapping), problems with attention and hyperactivity and social anxiety. A majority of individuals with Fragile X will have either Autism Spectrum Disorder or autistic symptoms, and will have varying levels of cognitive impairment. The FDA has not approved any drugs specifically for the treatment of Fragile X or its symptoms.

One of the Fragile X studies we completed included multiple behavioral assessments of 40 mice, comprising 20 Fmr1 knock-out mice and 20 control littermate wild type mice that were treated with metadoxine or placebo. The data showed significant improvement in behavioral outcomes assessed with this animal model, including contextual fear conditioning (a test primarily evaluating memory and learning), social interaction, rewarded T-maze alteration (a test for working memory) and Y-maze alternation (a test of learning and perseverance). All assessments were scored blindly (raters were not aware of the treatment each mouse received).

We believe that the positive outcomes we reported in this animal model warrant investigation in clinical trials to evaluate the safety and efficacy of MDX for treatment of Fragile X. We plan to initiate such clinical studies in 2014.

We have multiple claims in our issued patent as well as other U.S. pending patent applications that, if issued, would prevent the use by others of Metadoxine to treat ADHD, Fragile X Syndrome and other cognitive disorders. In addition, the FDA has granted Orphan Drug status to Metadoxine.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate significant revenue unless and until we obtain marketing approval of, and commercialize, MDX. As of December 31, 2013, we had an accumulated deficit of $18.7 million. Our financing activities are described below under Item 5 “Liquidity and Capital Resources.”

Our Strategic Plan

Our objective is to develop and commercialize proprietary pharmaceutical products for treatment of central nervous system disorders, and cognitive dysfunctions in particular. To this effect, we intend to conduct additional clinical trials for our most advanced product (MDX) and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies for MDX for the treatment of ADHD in adults and children. We also plan to advance clinical studies and commercialization plans for MDX in additional indications of cognitive dysfunction which present significant market opportunities, such as Fragile X Syndrome, where we announced positive results from pre-clinical studies. To achieve these objectives, we plan to:

- Ÿ complete two Phase 3 clinical trials of MDX for the treatment of ADHD in adults, and, if they are successful, file for marketing approval for adults in the U.S. (expected completion in the third quarter of 2015);

- Ÿ initiate and complete clinical trials in a pediatric ADHD population, and, if successful, file for marketing approval for that use in the U.S. (expected initiation in the second quarter of 2014 and expected completion of trials in the fourth quarter of 2015);

- Ÿ initiate and complete clinical trials in EU and Japan for both adult and pediatric ADHD, and, if successful, file for marketing approval of such uses in these regions);

- Ÿ prepare to commercialize MDX for the treatment of patients with ADHD by establishing distribution capabilities primarily in conjunction with large pharmaceutical companies;

- Ÿ complete the required clinical trials, that, if successful, would allow us to request drug approval of MDX to treat children and adults with Fragile X in the U.S. (expected initiation of the first trial in mid 2014 and expected completion thereof in 2015); and

- Ÿ conduct early stage clinical trials into the possible use of MDX to treat other cognitive disorders and impairments.

About ADHD

The ADHD Market

The U.S. market size for ADHD treatment is estimated to be over $5 billion annually, which accounted for approximately 90% of the global ADHD market. The difference in market sizes between the U.S. and other countries is driven by different rates of diagnosis and treatment, different pricing, and the number of available brand name medications (non-U.S. markets are dominated by generic drugs). Global prevalence rates of the disease are estimated to be approximately 8-10% of school-aged children and approximately 4-5% of the adult population. Adult diagnosis and treatment is forecast to grow in the near future due to increased disease awareness and less sociological stigmatization towards the condition. In the United States, the diagnosis rate is approximately 51% in children and 31% in adults with consequent treatment rates of approximately 70% in children and 49% in adults. Overall, the U.S. market is forecast to grow at a compound annual growth rate, or CAGR, of 7% per annum and reach $6.2 billion by 2018. The global ADHD market is forecast to grow at a CAGR of 8% in part because higher disease recognition and acceptance is expected in Japan and Europe. Also, the estimated growth for the non-U.S. markets is higher due to prospective approval dates for major ADHD drugs that have already been marketed in the U.S., such as Vyvanse and Intuniv. Despite upcoming patent expiration dates and the entry of several generic compounds, the market size is expected to grow further as new drugs enter the market and compensate for the generic erosion.

Development of ADHD Symptoms

Once perceived to only affect children, ADHD is now known to persist into adolescence and adulthood in a sizeable number of cases. The following graphic illustrates how the nature of ADHD symptoms changes with age:

Children	Adolescents	Adults
Hyperactive	**Easily distracted**	**Shifts activities**
Aggressive	**Inattentive**	**Easily bored**
Low frustration tolerance		**Impatient**
Impulsive		**Restless**

A recent study showed that approximately 50% of adults who suffered from ADHD as children continue to have symptoms of the disorder as adults, with over 90% experiencing attention deficit symptoms and about 35% of them experiencing hyperactivity- impulsivity symptoms. As the majority of sufferers of ADHD age, their symptoms tend toward impatience, restlessness, boredom and low concentration levels from the more aggressive hyperactivity and impulsive behavior evident in children.

Although the definitive causes of ADHD are still unclear, current research suggests that ADHD is caused by an interaction between environmental factors and genetic predispositions. Biologic factors that reportedly increase the risk of having ADHD include maternal smoking, drug or alcohol abuse during pregnancy, brain injury and exposure to toxins. Furthermore, diet may play a role in ADHD.

Impact of Untreated and Undertreated ADHD

ADHD is believed to be one of the most under-diagnosed and under-treated mental health conditions facing children and adults. ADHD increases health risks, adverse social externalities and economic costs as illustrated in the following table. Despite the disorder being highly treatable, most adults with ADHD remain undiagnosed and untreated.

The following illustrates the effects on society when ADHD remains untreated:

Healthcare System	**Patient**	**Family**
ñ 50% in bicycle accidents	ñ criminal activity	3-5x more divorce/separation
ñ 33% in ER visits	ñ incarceration	2-4x more sibling fights
2-4x more car accidents		
School and Occupation	**Society**	**Employer**
46% expelled	Substance use disorders:	Increased parental absenteeism and lower
35% drop out	2x risk and earlier onset	productivity
Lower occupational status	Less likely to quit in adulthood	

Diagnosis of ADHD

The diagnosis of ADHD is obtained by a psychiatric assessment which is intended to eliminate other potential causes. A formal diagnosis is completed by a qualified physician and is based on a number of set criteria. The Diagnostic and Statistical Manual of Mental Disorders, fourth edition, or DSM-V, diagnostic criteria are most widely used to diagnose ADHD.

Ÿ *DSM-V criteria*. The American Psychiatric Association provides a set of standardized criteria for classifying mental disorders known as the Diagnostic and Statistical Manual of Mental Disorders, or DSM. These criteria are based on the premise that attention deficits are distinct and differentiated conditions that are abnormalities resulting from biological origins that can be reliably and objectively measured. The diagnostic criteria include:

- Inattention – the patient makes careless mistakes in activities and is easily distracted
- Hyperactivity – the patients fidgets, squirms, talks excessively or displays restless behavior
- Impulsiveness – the patient interrupts others and cannot wait for a turn
- There must be clear evidence of significant impairment in social, school, or work functioning
- Signs of impairment present before twelve years of age and present in two or more settings (school/work and home)

- Signs are not better accounted for by another mental disorder

The DSM-V criteria are becoming more prevalent as the diagnostic measure for ADHD in Europe and Japan. If the DSM-V criteria are used, rather than an alternative measure in declining use, a diagnosis of ADHD is three to four times more likely. Consequently, the size of the market in Europe and Japan is set to grow with improved diagnosis rates driven by adoption of the DSM-V criteria.

Key Products – ADHD

The four drugs to treat ADHD that to our knowledge had the most sales in 2012 on a worldwide basis are shown in the following table, together with the drug brand name, owner, reported 2012 sales and historic or expected peak sales. Out of the drugs listed below, Vyvanse, Concerta and Adderall XR are stimulants and Strattera is a non-stimulant drug.

Brand (launch)	Generic Name	Owner	Sales in 2012 U.S. Dollars in Millions	Peak Sales U.S. Dollars in Millions
Vyvanse (2007)	Lisdexamfetamine	Shire	1,030	1,635 (2016)
Concerta (2000)	OROS Methylphenidate	J&J	1,073	1,326 (2009)
Adderall XR (2001)	Mixed Amphetamine Salts	Shire	429	1,102 (2008)
Strattera (2002)	Atomoxetine	Eli Lilly	621	667 (2004)

Limitations of Current Treatment Options for ADHD

Because of the significant side effects and abuse potential associated with current stimulant treatment options for ADHD which are classified in the same controlled substance category as narcotics, there is a significant need to develop safe and effective treatment alternatives.

Historically, the first line treatment for ADHD was stimulants, such as methylphenidate and amphetamine. These are classified as Schedule II controlled substances that can cause dependence and abuse. The danger of prescription drug abuse is one of the main causes of low treatment rates, particularly by primary care physicians (PCPs) who are the largest group of prescribers. All but one of the current drugs on the market to treat adult ADHD are stimulants. Strattera is the only drug currently on the market for adults with ADHD that is a non-stimulant. Strattera has been effective, but it also has serious side effects, such as fatigue, GI upset, sexual problems, palpitations, increased heart rate, blood pressure, and regulatory warning labels on suicidal thoughts and liver damage. Moreover, Strattera also takes six to ten weeks to achieve full clinical effects. MDX has low potential to be an abused drug, has shown efficacy after a single dose and improved safety profile, and we believe that its market entry should increase treatment rates and drive market growth.

While stimulants have been shown to be effective for the treatment of ADHD, up to 30% to 50% of those who are prescribed stimulants for ADHD either do not respond or cannot tolerate these treatments. Consequently, medication adherence rate for these ADHD therapies is poor, with less than 20% of patients continuing on therapy 12 months after they are first prescribed medication. Therefore, there is a significant need to develop safe and effective treatment alternatives, particularly ones devoid of abuse potential and significant side effects.

Clinical Data in ADHD

Symptom and Clinical Efficacy Measurement

There are various methodologies for evaluating and measuring changes in the symptoms of ADHD patients, including behavior rating scales, computer-based cognitive tests and verbal and pictorial performance tests. The key approved and widely accepted methodologies used to test the clinical efficacy of ADHD pharmacotherapies include:

Ÿ *Conners' Adult ADHD Rating Scales, or CAARS.* CAARS measures the presence and severity of ADHD symptoms to determine whether or not ADHD is a contributing factor to a patient's symptoms. The scales quantitatively measure the frequency and severity of ADHD symptoms across clinically significant areas using a 30-item questionnaire. The scale has been used extensively in clinical trials including pivotal adult Phase 3 studies of approved pharmacotherapies for ADHD. Behavioral rating scales, similar to the CAARS measure, but with questions relevant to children, are used for the assessment of ADHD symptoms in children.

- *Adult ADHD Quality of Life Questionnaire, or AAQoL.* AAQoL provides a validated disease-specific measure of the impact of ADHD on the quality of life. It is measured as an overall score (totaling 29 items) and four subscale scores including: life productivity (11 items), psychological health (6 items), life outlook (7 items) and relationships (5 items). It has been validated in clinical trials and used in the Phase 3 study of Atomoxetine (Strattera) in adults.

- *Test of Variables of Attention, TOVA.* TOVA is a computerized test that assists in the screening, diagnosis, and treatment monitoring of attention disorders such as ADHD. The test provides an objective, quantitative neurological measure of attention. The test consists of a 20-minute, simple "computer game" that measures responses to either visual or auditory stimuli. These measurements are then compared to the measurements of a group of people without attention disorders who complete the same test. The test provides information about a subject's response style, such as the tendency to make impulsive errors or errors due to inattention, distraction or reaction time. TOVA outcomes include sub-scores for Response Time Variability (a time measurement of how consistently a target signal is identified when a micro-switch is pressed throughout the test), Response Time (a time measurement of how fast or slow information is processed and how much time it takes an individual to react), Commission Errors (a measure of impulsivity: how many times an incorrect signal is identified when the micro-switch is pressed erroneously), and Omission Errors (a measure of inattention: how many times is the correct target signal missed when the micro-switch is not pressed). The TOVA also provides a calculated ADHD Score that provides a cumulative index. ADHD scores <-1.8 are considered outside the normative range for version 7 and scores <0 are considered outside the normative range for version 8.

Clinical Results

We have conducted several clinical trials in adult ADHD subjects in Israel testing the safety and efficacy of our novel non-stimulant drug candidate, MDX. These trials included:

- a Phase 2a open label proof of concept study of 38 adult ADHD subjects, followed by two extension studies to determine length of efficacy and optimized dosages; and

- a six-week, randomized, double-blind, placebo-controlled, parallel-group, multi-center Phase 2b study of 120 adult ADHD subjects, in which ADHD subjects were randomly assigned in a 1:1 ratio to one of two treatment groups : a 1,400mg dose of MDX and a matching placebo.

- a randomized, double-blind, placebo-controlled, cross-over single center Phase 2b study conducted in 36 adult subjects with PI-ADHD with 1400 mg MDX, 700 mg MDX and matching placebo

Additional information about our clinical trials is shown in the following chart.

	Phase 2a	First Phase 2b	Second Phase 2b
When the clinical study was held	Q1-Q2 2010	Q2-Q3 2011	Q3-Q4 2013
How long the clinical study was active	3 months	4 months	4 months
How we targeted subjects to enroll	Existing adult subjects in local ADHD treatment clinic	Existing adult subjects in local clinics; online advertisement; newspaper advertisement	Existing adult subjects in local ADHD treatment clinic and online advertisement
Whether we conducted the study with any other parties	No	No	No
The steps taken to ensure the accuracy of the results	Outside CRO oversight, including monitoring visits; outside medical monitor; double-typing of data in the data management system; automatic and manual query generation; and external expert review		

The Phase 2a study was designed to evaluate the effect on cognitive function of a single oral administration of MDX in subjects ranging from ages 18-45 who had been diagnosed as having ADHD. The study was performed at the ADHD unit of the Geha Mental Health Hospital (Israel). The primary outcome measures in the trial were the one-hour post-medication ADHD Score, and various TOVA subscores, Secondary outcome measures were subtests from the Wechsler Adult Intelligence Scale-Revised (WAIS-R test). The WAIS is a battery of tests designed to measure intelligence in adolescents and adults. WAIS includes both non-verbal performance scales as well as verbal intelligence items. A revised form of the WAIS, WAIS-R, consists of six verbal and five performance subtests. The verbal tests are: information, comprehension, arithmetic, digit span, similarities, and vocabulary. The performance subtests are: picture arrangement, picture completion, block design, object assembly, and digit symbol.

Results of this clinical study showed clinically and statistically significant improvement in all the TOVA parameters that were abnormal at baseline (see table below). “P values” are a measure of statistical significance. P is a statistical measure for the probability of an error. In clinical investigations, $p<0.05$ (meaning that the probability of an error in the outcome is less than 5%) is considered a statistically significant finding.

Parameter (n=38)	Change from baseline	p
Omission Score	+12.9 (+16.6%)	p<0.03
Commission Score	+6.9 (+7.5%)	p<0.01
Response Time Score	+12.9 (+12.2%)	p<0.02
Response Time Variability Score	+24.2 (+38.6%)	p<0.001
ADHD Score	+3.9 (+75%)	p<0.001

TOVA Subscores

Furthermore, results of the Wechsler subtests confirmed the ability of MDX to improve cognitive functions in adults with ADHD, with clinical and statistically significant improvement seen in both working memory and spatial memory tests. A significant correlation was found between the drug response measured by the TOVA and the response measured by the WISC subtests.

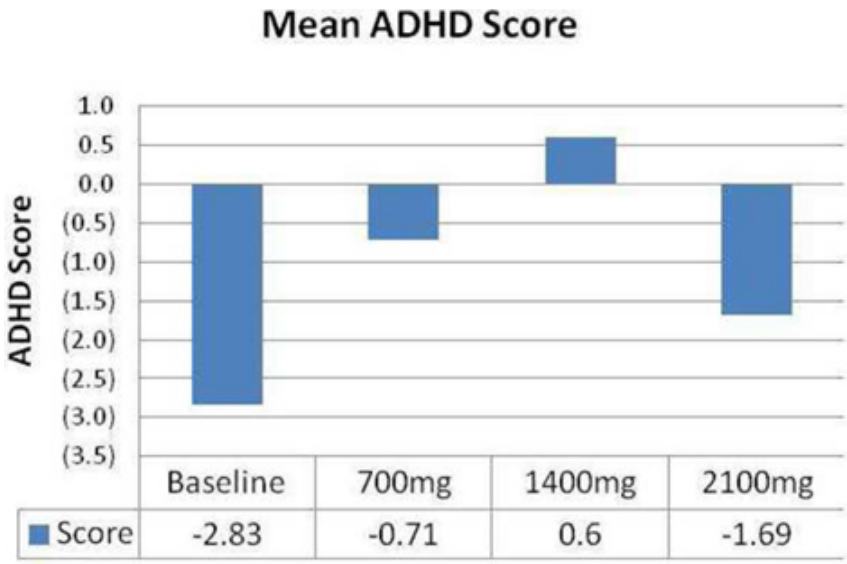
WAIS-R subtest (n-38)	Baseline mean (min,max)	Post medication mean (min,max)	Change	p
Correct Symbols	34.7 (18,59)	37.9 (22,57)	+3.4	p<0.001
Symbol Search	74.6 (54,119)	81.8 (61,118)	+7.2	p<0.001
Digits Forward	9.9 (5,14)	10.7 (7,14)	+0.7	p<0.003
Digits Backward	7.0 (3,13)	7.8 (2,14)	+0.9	p<0.01
Total Digits	16.9 (9,26)	18.6 (10,27)	+1.6	p<0.001

Wechsler Subscores

In a small extension study to study the duration of drug benefits, 10 subjects were evaluated using TOVA immediately before, and 90 minutes, 4 hours and 7 hours after, taking a single 1400mg dose of MDX. Data below show the mean TOVA scores in these subjects at the specified time points, showing an extended effect of the drug on cognitive functions. A TOVA score of -1.8 or less in version 7 is considered abnormal.

Mean ADHD Scores Following Single MDX Dosing

In another extension study designed to validate the MDX dose used in studies thus far, 10 subjects were evaluated using TOVA 90 minutes after blindly taking either 700mg, 1400mg or 2100mg doses of MDX on separate occasions. TOVA results following these treatments were compared to the baseline data obtained before any treatment in these subjects. Data below show the mean ADHD score in these subjects at baseline and following each of the three evaluated drug doses, establishing the likely effective dose range for MDX to be 700-1400mg, and demonstrating that the 1400 mg dose had the greatest magnitude of effect.



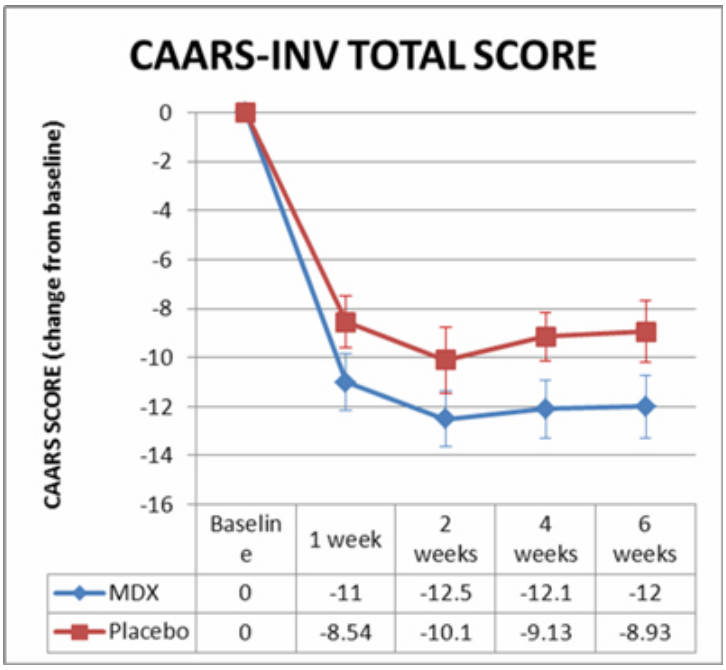
Mean ADHD Scores Before and 90 Minutes Following One of Three MDX Doses

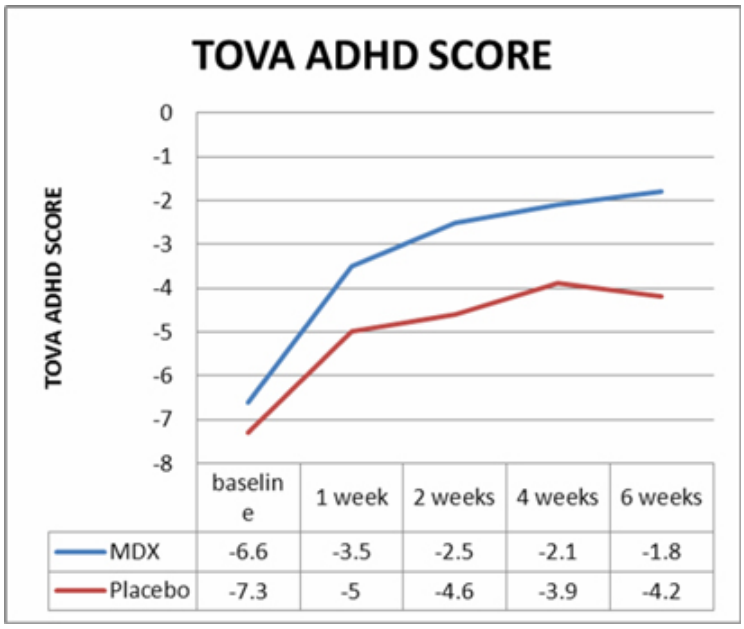
Summary of Phase 2b Clinical Study 1

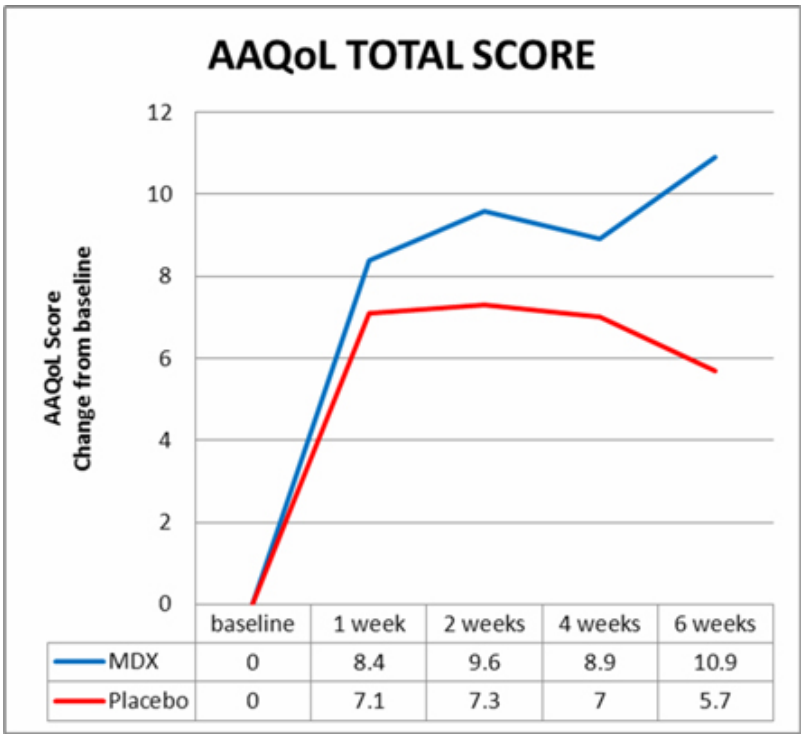
We completed a six-week randomized, double-blind, placebo-controlled, parallel-group, multi-center Phase 2b study in 120 adult subjects with ADHD that was performed in two centers in Israel: the ADHD unit at Geha Mental Health Hospital and the Cognitive Neurology unit at Rambam Healthcare Campus.

ADHD subjects were randomly assigned in a 1:1 ratio to one of two treatment groups: 1400mg MDX or matching placebo. The primary efficacy measure was the Conners' Adult ADHD Rating Scale – Investigator version Adult ADHD rating scale with adult prompts (CAARS) questionnaire, and the secondary efficacy measures were the TOVA test and the AAQoL questionnaire.

Significant improvements in CAARS scores ($p<0.02$), TOVA ADHD scores ($p<0.02$) and AAQoL scores ($p<0.01$) were observed in the MDX treated group versus the placebo group, as can be seen in the image below. Improvements in CAARS and TOVA scores were statistically significant over the placebo after as little as two weeks of treatment. Sub-analysis of subjects with ADHD inattentive type (n=48) showed an even greater improvement in CAARS scores over the placebo, as well as a larger response rate.


CAARS-INV TOTAL SCORE
CAARS SCORE (change from baseline)
0
-2
-4
-6
-8
-10
-12
-14
-16
Baseline
1 week
2 weeks
4 weeks
6 weeks
MDX 0 -11 -12.5 -12.1 -12
Placebo 0 -8.54 -10.1 -9.13 -8.93


TOVA ADHD SCORE
TOVA ADHD SCORE
0
-1
-2
-3
-4
-5
-6
-7
-8
baseline
1 week
2 weeks
4 weeks
6 weeks
MDX -6.6 -3.5 -2.5 -2.1 -1.8
Placebo -7.3 -5 -4.6 -3.9 -4.2



Physical examination, laboratory parameters, vital signs, and electrocardiograms showed no consistent differences between treatment groups or cumulative changes over time. The most commonly reported adverse events were nausea, fatigue and headache. Nausea was the only adverse event to occur exclusively in the MDX group and should be considered an anticipated event in future MDX research; fatigue occurred in similar numbers in both groups, and headache occurred notably less frequently in the MDX group.

Summary of Phase 2b Clinical study 2

We completed a Phase 2, randomized, double-blind, placebo-controlled, crossover comparison, single-center study in 36 adult subjects with Predominantly Inattentive ADHD (PI-ADHD). The study was designed to compare the efficacy, safety and tolerability of two doses of MDX, 1400 mg and 700 mg, and placebo for the treatment of symptoms in adults diagnosed with PI-ADHD. The primary efficacy endpoint of the study was met, as demonstrated by a significant difference between the change in TOVA ADHD score following single-dose administration of 1400 mg MDX versus Placebo (mean change 6.5 vs. 4.4 points, p=0.0084). The difference between the change in ADHD score following administration of 700 mg MDX and Placebo was not statistically significant. A significant difference was observed between the change in TOVA ADHD score between the 700 mg MDX and 1400 mg MDX with the 1400 mg MDX dose, resulting in a statistically significant improvement above the 700-mg MDX dose. Overall, the 1400 mg MDX dose was associated with a statistically significant improvement compared to 700 mg MDX and placebo as indicated by the primary endpoint of the study in adult subjects with PI-ADHD. Efficacy was demonstrated following a single dose of 1400 mg MDX but not after a single dose of 700 mg MDX, as measured 3-5 hours after drug administration. Both doses of MDX were associated with a favorable safety profile, particularly in comparison to no treatment (Pre-dose) and Placebo, per adverse event, laboratory (hematology, biochemistry, urinalysis), vital sign, ECG, and physical and neurological evaluations.

Summary of Clinical Data in ADHD and Key Conclusions

We have conducted three Phase 2 efficacy studies of metadoxine in adults with ADHD. Doses of MDX administered in the studies were 700 mg, 1400 mg, and 2100 mg MDX, and efficacy has been examined after both single and repeat doses. After a single dose of 1400 mg IR/SR MDX, an immediate response and clinically meaningful improvement in performance (as reflected by TOVA and WAIS-R scores) was seen, with improvements in response time and response time variability scores up to 7 hours post-dose. Administration of a single 1400 mg dose of MDX to adults with PI-ADHD resulted in similar changes in the TOVA. A comparison of the effect of single doses of 700 mg, 1400 mg, and 2100 mg extended-release metadoxine indicates the possible superiority of the 1400 mg dose. When this dose of MDX was administered over a 6-week period in adults with ADHD, there was a significant improvement in ADHD symptoms and subjects' quality of life responses compared with placebo and a possible differential effect on inattentive/cognitive function symptoms in the PI-ADHD subtype, as reflected by CAARS-INV and TOVA scores.

Improvement in inattention symptoms was statistically significant. One measure of effectiveness is called an “effect size” based on various statistical computations. An effect size of 0.4 with the CAARS was observed in the first Phase 2b trial of MDX. An effect size of 0.35-0.4 with the CAARS has been reported for Atomoxetine, the only approved non-stimulant medication of Adult ADHD. An effect size of 0.9 was calculated for the predominantly-inattentive ADHD population in our first Phase 2b study. This effect size is considered large and is in fact comparable to reported effect sizes of stimulant medications.

Adverse Events

In all studies, MDX was well tolerated. The most commonly reported adverse events in the various clinical studies were nausea, fatigue and headache. In the first Phase 2b study described above, transient moderate nausea, lasting from one to two days, was the only adverse event to occur exclusively in the MDX group, with an incidence of approximately 17%; fatigue was largely the same in the control groups (27%) and the MDX groups (31%), and headache occurred notably less frequently in the MDX group, in about 29% of the subjects, as compared with 38% of the subjects in the placebo group. In the second phase 2b study described above, the most common adverse events reported during the treatment period were fatigue and headache. There were no serious or severe adverse events in these three clinical trials, and no clinically significant treatment-related abnormalities in vital signs, electrocardiograms (ECG), physical examination, and clinical labs (hematology, chemistry, and urinalysis).

In addition, products containing metadoxine outside the United States cite infrequent diarrhea and moderate skin rash.

About Fragile X Syndrome

Description of Fragile X Syndrome

Fragile X Syndrome is a genetic disorder that is characterized by a high number (>200) of repeated DNA base sequences (called CGG repeats) in the X chromosome. Fragile X is diagnosed by a blood test that measures the amount of CGG repeats. These repeated sequences are associated with a change in the amount of Fragile X Mental retardation protein, or FMRP, produced by the cell. A greater reduction in FMRP is associated with more severe physical symptoms and intellectual disability. Through the regulation of protein levels in nerve cells in the brain, FMRP is thought to be involved with brain pathways that undergo change to facilitate learning and memory.

Fragile X is the most common single gene cause of intellectual disability and autism and an unmet medical need exists with no approved drugs for the treatment of Fragile X. Fragile X is named for the broken microscopic appearance of the X chromosome, one of the sex-linked chromosomes, that is observed in people with the syndrome. Fragile X occurs in 1 out of 4,000 males and in 1 out of 8,000 females, and females are usually less affected than males. Fragile X is a rare disease, as defined by the Orphan Drug Act.

Fragile X Syndrome Symptoms

Not every individual with the Fragile X mutation will show signs or symptoms of Fragile X, and disabilities will range from mild to severe. In males, Fragile X is associated with moderate to severe intellectual disability. The severity of the disability is linked to the degree to which the X chromosome has additional chemical attachments known as methyl groups. Males with a high amount of methyl groups attached to the X chromosome tend to have higher severity of intellectual disability, while males with a low amount of methyl groups may have mild intellectual disability or a learning disability. About 25% of females with Fragile X will have intellectual disability, and most females with Fragile X will have a learning disability. Since females with Fragile X have one normal X chromosome and one chromosome with Fragile X, and either of the two X chromosomes is active in a given cell, females tend to have milder symptoms than males. Both males and females with Fragile X may show delay in acquiring language skills early in their life.

Individuals with Fragile X often have a number of behavioral symptoms, including inattention, hyperactivity, impulsivity, autistic symptoms, shyness, aggression, social anxiety, hand flapping, hand biting, and high sensitivity to being touched. Autism spectrum disorder (ASD) is seen in approximately 30% of males and 20% of females with Fragile X, and an additional 30% of Fragile X individuals display autistic symptoms without having the ASD diagnosis. ADHD is commonly diagnosed in Fragile X, and has been reported to occur in 59-80% of individuals with Fragile X.

Fragile X is associated with characteristic physical features that can include long face, large head circumference, large testicles most noticeable after the onset of puberty, large ears, flexible joints including dislocatable hips at birth, prominent chin and forehead, flat feet, soft skin, floppy heart valve (mitral valve prolapse), curved spine and clubfoot. Acid reflux (also known as heartburn) and feeding problems are common in infancy, and there is a high rate of ear infections. Seizures are seen in 13-18% of males and 5% of females.

Treatments for Fragile X Syndrome and Their Limitations

The FDA has not approved any drugs specifically for the treatment of Fragile X or its symptoms. Individuals with Fragile X are treated based upon their symptoms. If the individual has ADHD or ADHD symptoms, the individual might be treated with ADHD medications, such as stimulants, atomoxetine and alpha-2 agonists (guanfacine or clonidine). If there are symptoms of aggression or irritability, the individual might be treated with antipsychotic medications. Anxiety symptoms might be treated with anti-anxiety drugs such as selective serotonin reuptake inhibitors (SSRIs). If there are seizures, the individual might be treated with anti-convulsant drugs.

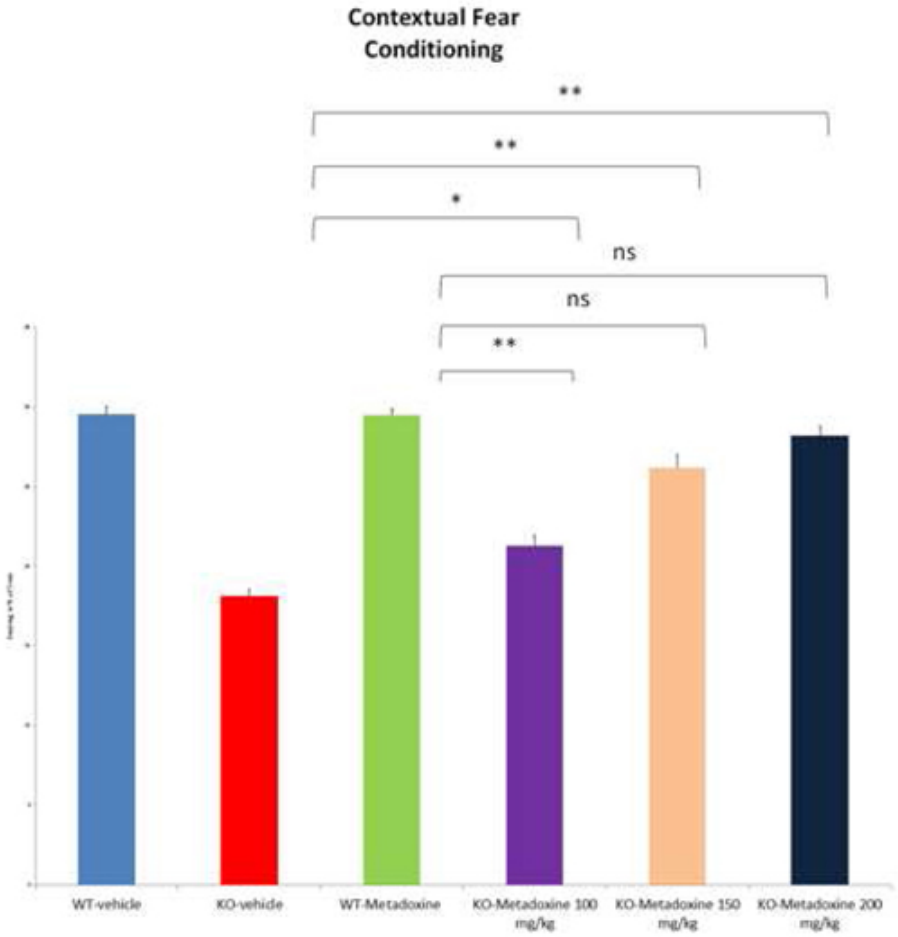
There are several drugs in clinical development for the treatment of Fragile X. Glutamate is the main excitatory neurotransmitter in the brain and is involved in cognitive functions like learning and memory. Glutamate receptors are responsible for the glutamate-mediated excitation of neural cells, and are important for neural communication, memory formation, learning, and regulation. Glutamate receptors are divided into two subfamilies, ionotropic glutamate receptors (NMDA, AMPA and kainate) and metabotropic glutamate receptors (mGluRs). FMRP has been shown to serve as a brake to the effects of the metabotropic glutamate receptor 5, or mGluR5, pathway in the brain, and with reduced FMRP in Fragile X, unopposed mGluR5 activation might be responsible for some of the behavioral and cognitive symptoms of Fragile X. Therefore, compounds that, reduce, or block the mGluR5 pathway might be beneficial in treating Fragile X. However, compounds that work via this pathway have been unsuccessful in clinical trials. AFQ056, an mGluR5 antagonist, failed to demonstrate efficacy in a Phase 2 trial. Arbaclofen, a GABA-B agonist which may reduce the effects of the mGluR5 pathway, also failed to demonstrate efficacy in a Phase 2 trial and two Phase 3 trials. Other drugs in clinical development for Fragile X include ganaxalone (neurosteroid that may modulate GABA-A), NNZ-2566 (Insulin Growth Factor 1 analog that may modulate mGluR5 signaling pathways), and RO4917523 (mGluR5 antagonist).

Data from Pre-clinical Study of Metadoxine in Fragile X

We have reported a series of positive findings from pre-clinical studies with a mouse model of Fragile X (Fmr1 knock-out mice). In the first study, metadoxine, the active ingredient in MDX, was shown to have significant dose-dependent effects on behavioral measures in 20 Fmr1 knock-out (KO) mice, in which the mouse version of the Fragile X gene is removed. 20 control littermate wild type mice were also included in this study. The Fmr1 KO mouse model is a validated model of Fragile X, as mice with a missing Fragile X gene demonstrate hyperactivity, susceptibility to seizures, enlarged testicles, learning and memory and social interaction impairments and abnormal brain connections, similar findings to those of individuals with Fragile X. In a controlled experiment with Fmr1 KO mice and wild type mice given either metadoxine or placebo, significant effects of metadoxine upon Fmr1 KO mice were observed on behavioral outcomes, including contextual fear conditioning (a test primarily evaluating memory and learning), social interaction, Y-maze alternation and the Rewarded T-maze (tests of learning and perseverance). All assessments were scored blindly (raters were not aware of the treatment each mouse received). These findings suggest the potential to translate into a clinical trial of MDX in Fragile X.

Contextual Fear Conditioning: Test of memory and learning

Contextual fear conditioning involves placing an animal in a novel environment, providing an aversive stimulus, and then removing it. When the animal is returned to the same environment, it generally will demonstrate a freezing response if it remembers and associates that environment with the aversive stimulus. Freezing is a species-specific response to fear, which has been defined as "absence of movement except for respiration". Contextual fear conditioning test is used to examine both hippocampus-dependent memory and amygdala-dependent emotional memory and learning.

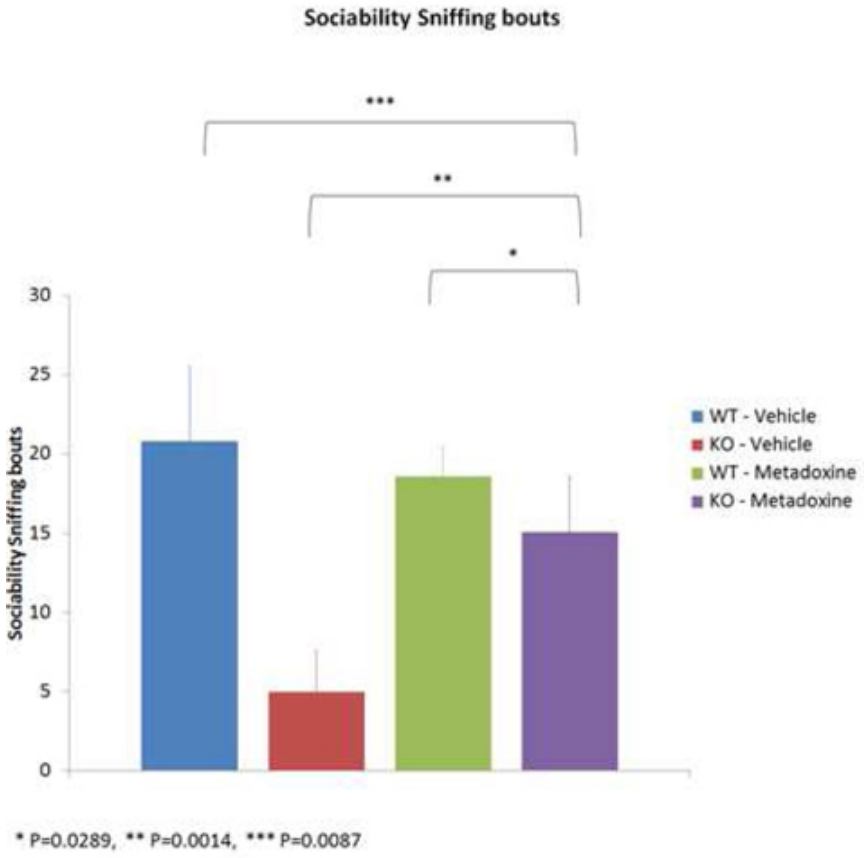


* p<0.05 ** p<0.01 Ns- non significant

Fmr1 KO mice treated with Metadoxine (KO-M) at concentrations ranging from 100 to 200 mg/kg exhibited a significant dose-dependent improvement in learning and memory when compared to the vehicle-treated Fmr1 KO group (KO-V). However, a significant difference (p<0.01) was found only between the WT Metadoxine-treated group (WT-M) and the Fmr1 KO mice treated with 100mg/kg of Metadoxine, suggesting that despite a significant improvement in the Fmr1 KO group receiving 100 mg/kg Metadoxine, only 150 and 200 mg/kg dose levels of Metadoxine fully rescued the Fmr1 KO mice learning deficit.

Social Interaction: A social approach

Social recognition and social memory in mice are evaluated by the amount of time spent sniffing a novel mouse upon repeated exposures to induce familiarity, and reinstatement of high levels of sniffing when a novel stimulus animal is introduced.

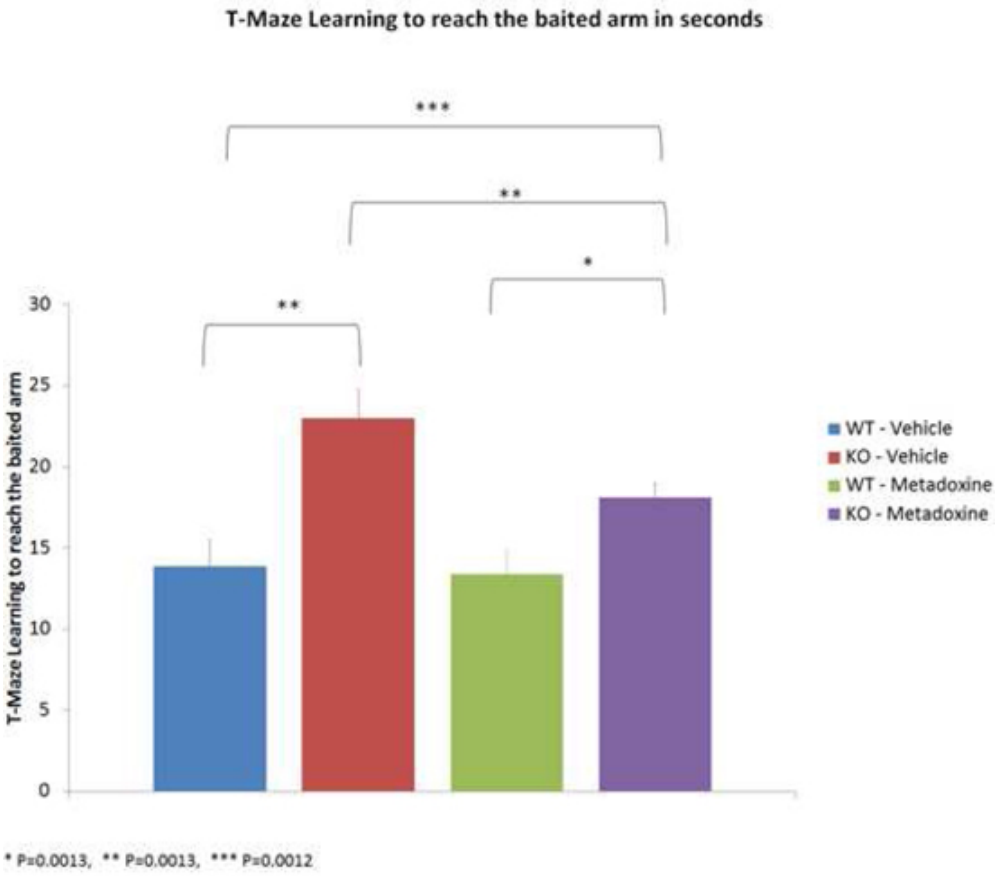


* P=0.0289, ** P=0.0014, *** P=0.0087

As expected, a significant reduction in sociability sniffing bouts was found ($p<0.0001$) between the KO-V and the WT-V. However, although KO-M mice (150 mg/kg) did show a significant difference when compared to WT-V and WT-M groups ($p<0.01$ and $p<0.05$, respectively), KO-M mice exhibited a significant improvement in social recognition as compared to KO-V, exhibiting very close levels to those of WT-V and WT-M levels and showing a trend of complete normalization.

Rewarded T Maze Alternation. Test of working memory

The T-maze learning task is used to detect impairment in spatial working memory skills. Animals are started from the base of the T and allowed to choose one of the goal arms abutting the other end of the stem. If two trials are given in quick succession, on the second trial the rodent tends to choose the arm not visited before, reflecting memory of the first choice. This is called 'spontaneous alternation'. The spontaneous rewarded alternation task is very sensitive to dysfunction of the hippocampus, but other brain structures are also involved.



* P=0.0013, ** P=0.0013, *** P=0.0012

As expected, KO-V mice displayed significantly increased latency to find the food pellet as reinforcement at the baited arm ($p<0.01$) as compared to the WT-V group due to impaired working memory. However, although KO-M mice (150 mg/kg) did show a significant difference when compared to WT-V and WT-M groups ($p<0.01$ and $p<0.05$, respectively), KO-M mice (150 mg/kg) exhibited significant decreased latency to reach the baited arm as compared to KO-V animals, suggesting improvement of spatial working memory and showing a clear trend of normalization to control levels.

In the second study, the positive findings in behavioral outcomes following treatment with Metadoxine (contextual fear conditioning and social interaction) observed in the previous study were highly reproducible. Improved cognitive and social functions were associated with reduction of brain and blood levels of over-activated biological markers, Akt and Extracellular signal-related Kinase (ERK) following treatment with Metadoxine in Fmr1 KO mice. The Akt and ERK pathways are thought to play a critical role in impaired synaptic plasticity underlying learning and memory in Fragile X Syndrome patients.

This finding raises the possibility of using this effect as a screening tool in future clinical investigations for identifying patients who are more likely to respond to treatment and monitoring their response over time.
Additional findings from this study showed that Metadoxine treatment prevented the overabundance of poorly shaped, immature neurons in the hippocampal region of the brain and reduced exaggerated new protein synthesis in the same brain region. Overabundance of immature neurons and increased protein synthesis have been implicated in the pathophysiology of Fragile X Syndrome and are presumed to be responsible for impaired learning and memory.

MDX Overview and Mechanism of Action

MDX is a proprietary, combined rapid onset/extended release formulation of the chemical Pyridoxine Pyroglutamate, which is more broadly known as Metadoxine. Our internal studies suggest that Metadoxine attaches to and antagonizes a unique protein in the brain called the serotonin 5-HT_{2B} receptor, thereby reducing binding of the natural molecules that normally attach there. This receptor has been associated with ADHD in studies exploring the hereditary basis of ADHD, as well as in studies that attempt to understand the molecular basis of this and other cognitive disorders. MDX consists of a single oral tablet, which includes both a rapid onset release Metadoxine formulation and a slow release Metadoxine formulation together providing the desired dual release profile. The new extended-release formulation prolongs the human plasma levels of Metadoxine for up to 12 hours, which results in enhanced efficacy benefits.

Metadoxine has been available since the 1980s in immediate release forms for the acute treatment of alcohol intoxication and the chronic treatment of alcoholic liver disease. Metadoxine was approved for these indications in Italy, Portugal, Hungary, Russia, India, China, Mexico and Thailand. A literature survey covering over 20 years of post-marketing surveillance identifies only a few cases of minor adverse events. To our knowledge, no drug-related serious adverse events have ever been reported. We have multiple claims in our issued patent as well as other U.S. pending patent applications that, if issued, would prevent the use by others of Metadoxine to treat ADHD, Fragile X Syndrome and other cognitive disorders.

Normally, the levels of neurotransmitters in the brain, such as dopamine, norepinephrine and serotonin, are fully regulated in order to ensure proper neurological function and neuron-to-neuron communication. Communication between neurons is achieved by the controlled release of neurotransmitters from one neuron, their transport by a dedicated transporter across the synapse (the gap between two neurons) to another neuron, and their binding and internalization into the target neuron using a unique, designated receptor. One of the purported causes of the symptoms of ADHD is low levels in the brain of these neurotransmitters causing the lack of regulation of neuronal networks. In the design of pharmacological treatments for ADHD, low neurotransmitter levels can be modulated and reversed through enhancing the release, delivery and/or blocking the reuptake of neurotransmitters by their respective plasma transporters/receptors. All stimulants increase dopamine and norepinephrine levels. Atomoxetine (Strattera), the only non-stimulant approved for ADHD in adults, works through modulating norepinephrine. Our recent preclinical studies employed standard microdialysis techniques to sample and quantify the levels of these neurotransmitters in brains of rats, as well as imaging studies (1H-MRS) to further quantify levels of these neurotransmitters and their metabolites in different regions of the brain following single oral administration of metadoxine. We found no changes in levels of dopamine, norepinephrine or serotonin in rat brains following administration of MDX (or Metadoxine) in either evaluation. No changes in metabolites were observed. This is in contrast to the clear elevation of these neurotransmitters on their targets evident after treatment with existing ADHD pharmacotherapies. Moreover, enhanced dopamine levels are thought to be associated with increased potential of dependence and abuse. Therefore, Metadoxine was tested in the self-administration rat model to assess its abuse potential. In an experiment in which rats were trained to press a lever and self-administer the class II controlled abused drug, methylphenidate. As expected, methylphenidate was observed to be a positive reinforcer for pressing, while metadoxine had a level of pressing similar to that of a saline control. Overall, the data predict that metadoxine is working via a distinct novel mechanism of action in ADHD and is highly unlikely to become an abused drug in humans.

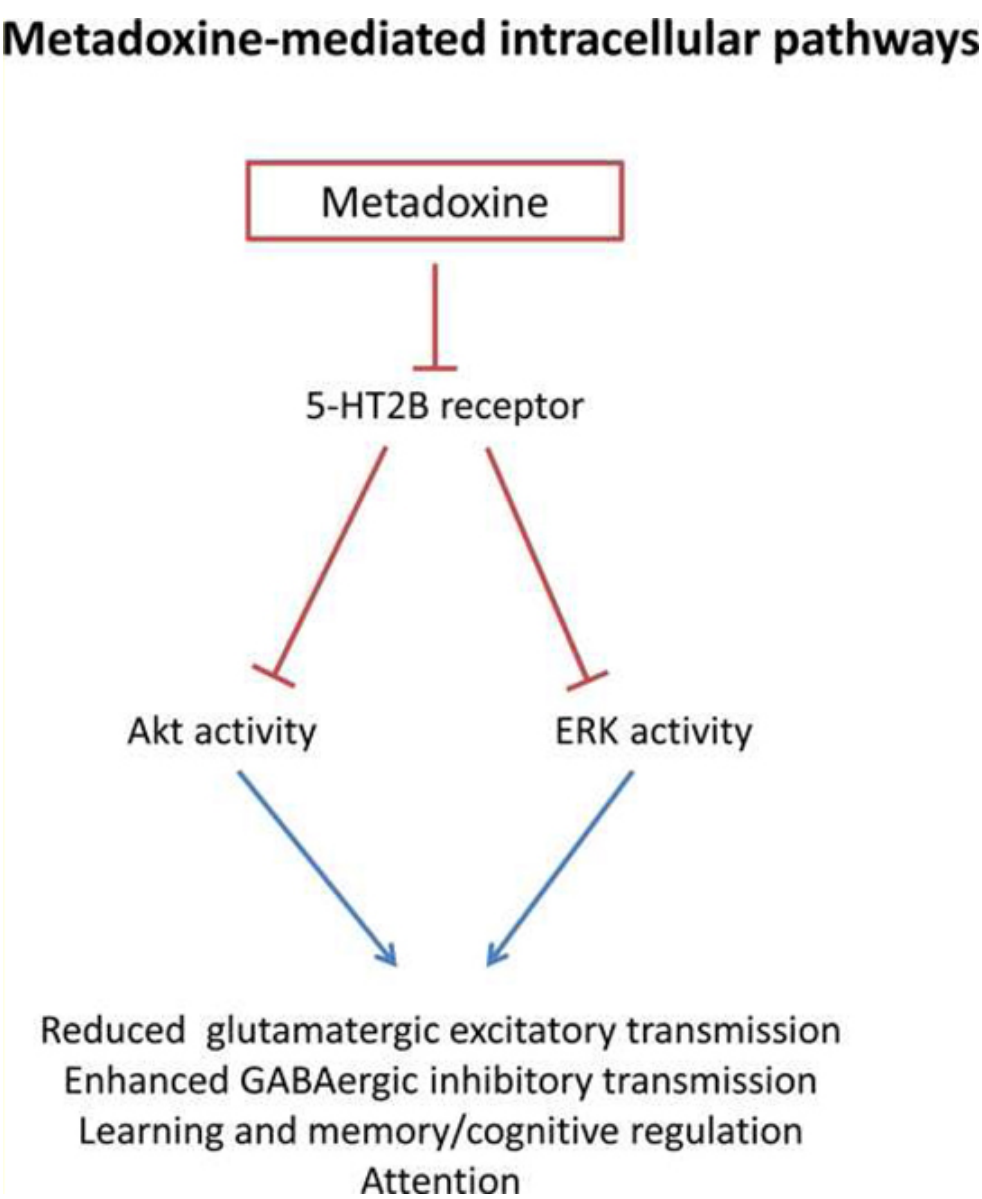
The neural networks operating in the brain are directed by various receptors and associated signals. One way to affect these networks is to identify a drug that binds to the site and inhibits the action of the protein or signal. In investigating the proposed mechanism of action for MDX, over 80 different cellular targets, such as receptors and transporters, were tested in the laboratory for binding with Metadoxine. Binding of Metadoxine was tested on targets that are part of the muscarinic, adrenergic, dopamine, serotonin, glutamate and GABA, noradrenaline, opioid and cannabinoid networks. These networks each function to orchestrate different activities and signals in different regions of the brain using different protein agents. Metadoxine displayed extensive and highly specific receptor binding to only one of the serotonin receptors family named 5-HT2B that has been implicated genetically in ADHD. The specific binding was further characterized by an assay in rat stomach fundus aimed at measuring whether Metadoxine is an activator (agonist) or a deactivator (antagonist) to the 5-HT2B receptor. This assay concluded that Metadoxine shows no agonist activities to this receptor, while its entire activity is as an antagonist. The binding had approximately 50-fold selectivity over all other 5-HT receptor subtypes and a variety of other receptors. Moreover, no binding was detected to any of the receptors or transporters involved in the brain networks controlled by dopamine or noradrenaline. Specifically, and in contrast to many approved ADHD pharmacotherapies, no binding was detected to the Dopamine, Norepinephrine or Serotonin transporters. Selectivity in binding is important because the goal is to bind only with the targeted receptor to achieve the desired therapeutic effect and not bind to other receptors where it may have undesired side effects. Therefore, MDX displays a novel mechanism of action because it is the only ADHD drug candidate which exclusively affects and antagonizes the 5-HT2B serotonin receptor without affecting other targets.

We have conducted studies with Metadoxine in a mouse model of Fragile X. We found that Metadoxine significantly improved memory and learning during the contextual fear paradigm in a dose-dependent manner, and the two highest dose levels (150 and 200 mg/kg) fully rescued the Fmr1 KO mice learning and memory deficit. Furthermore, a significant improvement in memory in the fmr1 KO mice treated with 150 mg/kg of Metadoxine was found in other behavioral tests, such as the T-maze, showing significant improvement in cognitive outcomes. These findings were supplemented by improved social interaction of KO mice treated with 150 mg/kg of Metadoxine.

Importantly, improved cognitive function, working memory and social interaction following treatment with Metadoxine (150 mg/kg) in a valid mouse model of Fragile X highly correlated with normalization of biochemical markers reflective of neuronal signaling pathways measured from whole brain preparations of these animals. Specifically, the increased activation of two regulatory proteins, as reflected by increased phospho-ERK1/2 (pERK1/2) and phospho-AKT (pAKT) observed in the affected animals treated only with placebo, were normalized to the levels seen in non-affected animals after treatment with Metadoxine, as indicated by a significant reduction of pERK1/2 and pAKT levels. It should be noted that other pathways thought to be activated after dopamine and norepinephrine signaling in the cell, such as the pathway controlled by the cyclic-AMP (cAMP) molecule and the PKA protein were not affected by Metadoxine treatment. Confirmation of these findings was seen in another study, in which improved cognitive and social functions were associated with reduction of blood and brain levels of over-activated Akt and Extracellular signal-related Kinase (ERK) in Fmr1 Knock-out mice.

Our working hypothesis is therefore that treatment of metadoxine, a selective antagonist of 5-HT2B receptors may inhibit Akt and ERK signaling, and thus mediate a potential therapeutic benefit in neuronal impairment by facilitating synaptic plasticity underlying learning and memory. In support of this hypothesis, we recently observed a dose-dependent reduction of glutamatergic transmission and enhanced GABAergic inhibitory transmission via pre-synaptic modulations in striatal medium spiny neurons in an electrophysiological study with metadoxine. In this study, Metadoxine appears to alter the balance of excitation/inhibition in synaptic transmission and may rescue neuronal hyperexcitability and neuronal circuit dysfunctions observed in several neurodevelopmental disorders, such as Fragile X and ADHD.

In summary, we believe that MDX demonstrates a novel and unique mechanism of action as a selective serotonin 5-HT2B antagonist, as well as a modulator of brain excitatory and inhibitory networks. Moreover, the 5-HT2B receptor is implicated genetically and physiologically as a possible etiologic factor in the development of ADHD, creating the potential for MDX to be an effective treatment for ADHD. Additionally, we believe that the findings discussed above display a unique pathway of activity not involving direct modulation of catecholamine concentrations or their downstream targets, but rather the disrupted neuronal signaling pathways in the cell that may be altered by Metadoxine.



Commercialization

We do not have any internal sales or distribution infrastructure. In the event we receive regulatory approval for MDX, we intend, where appropriate, to pursue commercialization relationships with pharmaceutical companies and other strategic partners providing for distribution through their sales and marketing organizations in order to gain access to global markets. Over the longer term, we may ultimately build an internal commercial infrastructure.

Third-Party Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governments, including Medicare and Medicaid, managed care providers, and private insurance plans. Decisions regarding the extent of coverage and amount of reimbursement to be provided for MDX will be made on a plan by plan basis.

Within the Medicare program, as a self-administered drug, MDX would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These Part D plans negotiate discounts with drug manufacturers, which may be passed on to each of the plan's enrollees. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by recent legislation will reduce this patient coverage gap, known as the donut hole, by reducing patient responsibility in that coverage range.

An ongoing trend has been for third-party payors, including the United States government, to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations tend to result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affect reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal and state proposals to implement controls on reimbursement and pricing, directly and indirectly.

Research and Development

We are conducting development activities to expand the commercial potential of MDX. We sponsor and conduct clinical research activities with investigators and institutions to measure key clinical outcomes that are necessary in order for us to be able to file an NDA with the FDA and equivalent filings with other regulatory authorities. For the years ended December 31, 2013, 2012 and 2011, we incurred $7,066,000, $818,000 and $1,822,000, respectively, of research and development expense.

Our previous clinical studies have been conducted at two established medical institutions in Israel, the ADHD clinic of the Geha Mental Health Hospital and the Cognitive Neurology unit at Rambam Healthcare Campus. We entered into customary clinical trial agreements in 2011 and 2013 with each of the institutions. The clinical trial agreements are in customary form and provide financial support for personnel, equipment, laboratory tests and filing during the clinical trial through payment to the research fund of the medical institution. The agreements were terminated with the conclusion of the clinical trials, and the finalization of the Clinical Study Report. The principal investigators at these institutions were Dr. Iris Manor (Geha) and Dr. Rachel Ben Hayun (Rambam) (Ichilov). All clinical and nursing staff was compensated entirely by their employer institution. We do not have any other business relationship with any of the investigators.

We commenced a Phase 3 clinical trial in adults with ADHD with our MDX product candidate in the first quarter of 2014. In connection with such efforts we engaged third parties, including a CRO. The trial is being conducted at 20 clinical sites: 18 in the United States and 2 in Israel.

Grants from the Office of the Israeli Chief Scientist

Our research and development efforts, during the period between May 1, 2009 and April 30, 2010, were financed in part through royalty-bearing grants, in an amount of $106,494 that we received from the OCS. With respect to such grants we are committed to pay certain royalties. Regardless of any royalty payment, we are further required to comply with the requirements of the Research Law with respect to those past grants. When a company develops know-how, technology or products using OCS grants, the terms of these grants and the Research Law restrict the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the OCS. We do not believe that these requirements will materially restrict us in any way.

Manufacturing

We currently have no manufacturing facilities and no personnel with commercial-scale manufacturing experience. We currently rely on one third-party manufacturers, ChemCon, located in Germany and Patheon Inc., which is located in Cincinnati, Ohio, to produce bulk drug substance and drug products required for our clinical trials, respectively. We have entered into a customary clinical trial material manufacturing agreement with Patheon. Supply under the agreement is done by purchase orders, there are no minimum purchase requirements or unusual financial arrangements and the agreement is terminable at will by either party. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our drug product candidates if and when we receive approval for marketing by the applicable regulatory authorities.

We have not identified a secondary fill/finish supplier. We do not have a long-term commercial supply arrangement in place with any of our contract manufacturers. If we need to identify an additional fill/finish manufacturer, we would not be able to do so without significant delay and likely significant additional cost.

Our third-party manufacturers, their facilities and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet, and continue to meet, cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Competition

We face competition from established pharmaceutical companies that currently market a wide range of drugs to treat ADHD and symptoms of Fragile X. All of these competitors have far greater marketing and research capabilities than we do. We also face potential competition from academic institutions, government agencies and private and public research institutions, among others, which may in the future develop products to treat ADHD and Fragile X. All of these companies and institutions may have products in development that are superior to MDX. Our commercial opportunity would be reduced significantly if our competitors develop and commercialize products that are safer, more effective, more convenient, have fewer side effects or are less expensive than MDX. Public announcements regarding the development of competing drugs could adversely affect the price of our stock and the commercial potential of MDX.

Intellectual Property

We seek patent protection in the United States and internationally for MDX and any other products that we may develop. Our policy is to pursue, maintain and defend patent rights developed internally and to protect the technology, inventions and improvements that are commercially important to the development of our business. Our portfolio of patent applications that cover the release formulations and pharmacokinetic profile of Metadoxine, including our special sustained release, combined release and burst release formulations and the associated methods of treatment.

Our one issued patent has been issued by the U.S. PTO. We cannot be sure that any additional patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. There is also a significant risk that any issued patents will have substantially narrower claims than those that are currently sought. Even with respect to any patents that may be issued to us, we cannot be sure that any such patents will be commercially useful in protecting our technology. Any patents issued with respect to our current patent applications would expire from 2028 to 2030. We also rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors — Risks Related to Our Intellectual Property.”

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us because metadoxine is manufactured and used in a number of foreign countries in other applications and is widely available. The manufacture of metadoxine and its use in other indications will not infringe our intellectual property rights, and will make it more difficult to monitor and enforce any patent rights that may be issued to us.

Our success depends in part on our ability to:

- Ÿ preserve trade secrets;
- Ÿ prevent third parties from infringing upon our proprietary rights; and
- Ÿ operate our business without infringing the patents and proprietary rights of third parties, both in the United States and internationally.

We also protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Regulation

Clinical trials, the drug approval process, and the marketing of drugs are intensively regulated in the United States and in all major foreign countries.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or IRB of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

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

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of MDX or any future product candidates or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before drugs may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests;
- submission of an IND application which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of an NDA which must occur before a drug can be marketed or sold.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any approvals for MDX will be granted on a timely basis if at all.

We will need to successfully complete extensive additional clinical trials in order to be in a position to submit a new drug application to the FDA. Our planned future clinical trials for MDX may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a study;

- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;

- obtaining institutional review board approval to conduct a study at a prospective site;

- recruiting subjects to participate in a study; and

- supply of the drug.

We must reach agreement with the FDA on the proposed protocols for our future clinical trials in the U.S. A separate submission to the FDA must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each study subject. Regulatory authorities, an IRB, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

Our objective is to conduct additional clinical trials for MDX in adults and children and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies. To achieve this objective, we have initiated and plan to complete two Phase 3 clinical trials of MDX for the treatment of ADHD in adults, and, if it is successful, file for marketing approval for adults initially in the United States and the European Union. We completed a Phase 2b trial in 2011 and plan to begin these Phase 3 studies in 2013. We plan to follow this process also with respect to the other cognitive disorders that we discuss herein, such as pediatric ADHD and Fragile X.

For purposes of NDA approval, human clinical trials are typically conducted in phases that may overlap.

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects.

- *Phase 2.* This phase involves trials in a limited subject population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase 2 studies may be sub-categorized to Phase 2a studies which are smaller, pilot studies to evaluate limited drug exposure and efficacy signals, and Phase 2b studies which are larger studies testing more rigorously both safety and efficacy.

- *Phase 3.* This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded subject population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

All of these trials must be conducted in accordance with good clinical practice requirements in order for the data to be considered reliable for regulatory purposes.

Typically, if a drug product is intended to treat a chronic disease, as is the case with MDX when it is intended to treat ADHD and Fragile X, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for MDX or any future product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The NDA Approval Process

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment unless a waiver or exemption applies (such as with Orphan Drug Designation). The application includes all relevant data available from pertinent non-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Based on pivotal Phase 3 trial results submitted in an NDA, upon the request of an applicant, the FDA may grant a priority review designation to a product, which sets the target date for FDA action on the application at six months, rather than the standard ten months. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with good clinical practices, or GCPs. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources, and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for MDX.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the NDA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for MDX, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Orphan Drug Designation

We received Orphan Drug Designation for Metadoxine, the active ingredient in MDX for the treatment of Fragile X Syndrome in the United States.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan Drug Designation is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven year term of market exclusivity upon final FDA approval, orphan drug designation also positions a company to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of expensive FDA user fees for the potential submission of a New Drug Application, and certain tax credits. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

FDA Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping and reporting of adverse experiences with the drug. Drug manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality and purity characteristics that it purports to have. Certain states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, fail to approve any NDA or other application, require us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of the NDA for that drug. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures and injunctive action.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of drugs. While doctors are free to prescribe any drug approved by the FDA for any use, a company can only make claims relating to the safety and efficacy of a drug that are consistent with FDA approval, and is allowed to actively market a drug only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of drugs.

Pediatric Research Equity Act

The Pediatric Research Equity Act, or PREA, amended the FDCA to authorize the FDA to require certain research into drugs used in pediatric patients. The intent of the PREA is to compel sponsors whose drugs have pediatric applicability to study those drugs in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. The Secretary of Health and Human Services may defer or waive these requirements under specified circumstances.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Anti-Kickback Statute, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

In the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including, but not limited to, the Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, beginning in 2013, a similar federal requirement will require manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Patient Protection and Affordable Health Care Act

As mentioned, in March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. The fees, discounts and other provisions of this law are expected to have a significant negative effect on the profitability of pharmaceuticals.

Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA would have on our business.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

4.C. Organizational structure

Our sole wholly-owned subsidiary is Alcobra, Inc., incorporated in the United States.

4.D. Property, plants and equipment

Our headquarters is currently located in Tel Aviv, Israel and consists of approximately 3,200 square feet of leased office space under a lease for three years. We have also leased an additional office in Petah Tikva, Israel of approximately 1,400 square feet. Our wholly owned subsidiary, Alcobra Inc., has signed a lease commencing April 1, 2014, to lease an office for our U.S. employees in the greater Philadelphia area, of approximately 500 square feet. We believe that our existing and planned facilities are adequate to meet our current needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

We consider that our current office space is sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Overview

We are an emerging biopharmaceutical company primarily focused on the development and commercialization of our proprietary drug candidate, MDX, to treat Attention ADHD and, potentially, additional cognitive dysfunctions, such as Fragile X. The most common currently available treatments for ADHD are stimulants that increase the brain chemicals dopamine and norepinephrine. Stimulants have significant side effects, and as controlled substances, have significant potential for misuse, abuse and addiction. MDX is a non-stimulant with a different mechanism of action. In September 2011, we completed a 120 subject double-blind placebo-controlled Phase 2 study in adult ADHD subjects in Israel that showed significant improvement in clinical ADHD symptoms, and also showed favorable tolerability with no significant side effects over a placebo. The trial met all primary and secondary clinical endpoints showing statistically significant improvement over the placebo-treated control group.

We have initiated Phase 3 clinical trials in the United States for the use of MDX to treat ADHD in adults. If these and any future clinical trials demonstrate the safety and efficacy of MDX, we will seek to obtain marketing approval from the FDA for MDX for use in adults. We have similar plans to seek marketing approval in the European Union and later in Japan.

Subject to obtaining the necessary regulatory clearances, we further plan to conduct a Phase I/II study in children and adolescents with ADHD in 2014, followed by a Phase 3 study in this population in 2015, and, if the data supports it, proceed to request a marketing authorization. In addition, we completed a pre-clinical study in mice that suffer from Fragile X and the positive outcomes we reported in this animal model we believe warrant investigation in clinical trials to evaluate the safety and efficacy of MDX for treatment of Fragile X. We plan to initiate such clinical studies in 2014.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate significant revenue unless and until we obtain marketing approval of, and commercialize, MDX. As of December 31, 2013, we had an accumulated deficit of $18.7 million.

Operating Expenses

Our current operating expenses consist of two components – research and development expenses, and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of expenses related to third party clinical consultants and expenses related to conducting clinical and preclinical trials, salaries and related personnel expenses, share-based compensation expenses, travel expenses and other research and development expenses.

Our research and development expenses consist primarily of expenses related to conducting clinical and preclinical trials, salaries and related personnel expenses, share-based compensation expenses, cost of third party clinical consultants and travel expenses and other research and development expenses.

The following table discloses the breakdown of research and development expenses:

	December 31,		
(in thousands of U.S. dollars)	**2013**	**2012**	**2011**
Cost to third party clinical consultants and expenses related to conducting clinical trials	$ 5,841	$ 663	$ 1,464
Salaries and related personnel expenses	590	56	161
Share-based compensation	430	*)	18
Travel expenses	97	48	81
Other expenses	108	51	98
Total	7,066	$ 818	1,822

*) Represents an amount less than $1.

We expect that our research and development expenses will materially increase as we have recently initiated additional clinical activity and prepare to conduct in clinical trials in MDX in the near future.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related personnel expenses, share-based compensation expense, professional service fees for accounting, legal and bookkeeping and other general and administrative expenses.

The following table discloses the breakdown of general and administrative expenses:

	December 31,		
(in thousands of U.S. dollars)	**2013**	**2012**	**2011**
Share-based compensation	$ 1,110	$ 26	$ 1,535
Professional services	1,065	211	102
Salaries and related personnel expenses	789	331	342
Travel expenses	131	53	-
Other expenses	129	62	105
Total	3,224	683	2,084

Results of Operations

	December 31,		
	2013	**2012**	**2011**
	(in thousands of U.S. dollars)		
Research and development expenses	$ 7,066	$ 818	$ 1,822
General and administrative expenses	3,224	683	2,084
Operating loss	10,290	1,501	3,906
Financial Expense, net	197	78	23
Tax Expenses	61		
Net Comprehensive loss	$ 10,548	$ 1,579	$ 3,929
Deemed dividend	-	-	180
Net loss attributable to holders of ordinary shares	$ 10,548	$ 1,579	$ 4,109

Comparison of the Year ended December 31, 2013 to the Year Ended December 31, 2012 to the Year Ended December 31, 2011

Research and development expenses

Our research and development expenses for the year ended December 31, 2013, amounted to $7,066,000, representing an increase of $6,248,000, or 763% compared to $818,000 for the year ended December 31, 2012. The increase is primarily due to an increase in third party clinical consultants expenses and expenses related to conducting clinical trials in an amount of $5,178,000, an increase of $534,000 in salaries and related personnel expenses reflecting an increase in the number of employees and salary increases and an increase of $430,000 for share based compensation expenses.

Our research and development expenses for the year ended December 31, 2012, amounted to $818,000, representing a decrease of $1,004,000, or 55%, compared to $1,822,000 for the year ended December 31, 2011. The decrease was primarily attributable to a reduction of payroll related expenses in an amount of $105,000, reflecting a decrease in the number of employees engaged in research and development related activities from four to one, and a reduction of expenses related to third party clinical consultants and other expenses related to conducting clinical trials in an amount of $801,000. The reduction in our research and development expenses was a result of a decrease in available funds and a decrease of research and development activity that took place after our clinical trials completed. Following clinical trial completion in 2011, research and development was limited to clinical study report writing, regulatory preparation and document collection, and study data presentations.

General and administrative expenses

Our general and administrative expenses totaled $3,224,000 for the year ended December 31, 2013, an increase of $2,541,000, or 372%, compared to $683,000 for the year ended December 31, 2012. The increase resulted primarily from an increase of $1,084,000 in share-based compensation expenses, an increase of $458,000 in salaries and related personnel expenses, an increase of $854,000 in professional services and an increase of $78,000 in travel expenses.

Our general and administrative expenses totaled $683,000 for the year ended December 31, 2012, a decrease of $1,401,000, or 67%, compared to $2,084,000 for the year ended December 31, 2011. The decrease resulted primarily from a decrease of $1,509,000 in share-based compensation expenses, an increase of $109,000 in professional services and an increase of $53,000 in travel expenses.

Operating loss

As a result of the foregoing, our operating loss for the year ended December 31, 2013, was $10,290,000, as compared to an operating loss of $1,501,000 for the year ended December 31, 2012, an increase of $8,789,000, or 585%.

Operating loss for the year ended December 31, 2012, was $1,501,000, as compared to an operating loss of $3,906,000 for the year ended December 31, 2011, a decrease of $2,405,000, or 62%.

Financial expense

We recognized financial expenses of $197,000 for the year ended December 31, 2013, representing an increase of $119,000, or 122%, compared to financial expenses of $97,000 for the year ended December 31, 2012. The financial expenses are related mainly to the conversion of our convertible notes converted during 2013.

For the year ended December 31, 2012, we recognized financial expenses of $78,000 representing an increase of $55,000, or 239%, compared to financial expenses of $23,000 for the year ended December 31, 2011.

Tax Expenses

We recognized $61,000 of tax expenses for the year ended December 31, 2013, which are the tax liabilities of our wholly owned subsidiary, Alcobra Inc. resulting from services Alcobra Inc. provides us in accordance with an arms' length services agreement.

Loss

As a result of the foregoing, our loss for the year ended December 31, 2013 was $10,548,000, as compared to $1,579,000 for the year ended December 31, 2012, an increase of $8,969,000, or 568%.

Our loss for the year ended December 31, 2012 was $1,579,000, as compared to $3,929,000 for the year ended December 31, 2011, a decrease of $2,350,000, or 60%.

Financial Expense and Income

Financial expense and income consist of financial expenses related to our convertible notes converted during 2013, bank fees and other transactional costs, exchange rate differences, and interest earned on our cash, cash equivalents and short-term bank deposits.

Critical Accounting Policies and Estimate

We describe our significant accounting policies more fully in Note 2 to our financial statements for the year ended December 31, 2013. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations.

We prepare our financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

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

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company”, we elected to rely on other exemptions, including without limitation, (i) providing an auditor’s attestation report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes - Oxley Act 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, “Compensation - Stock Compensation,” or ASC 718, which requires companies to estimate the fair values of equity-based payments awards on the date of grant using an option-pricing model. The value of the stock options is recognized as an expense over the requisite service periods in our statement of operations. We recognize compensation expenses for the value of our awards granted based on the accelerated method over the requisite service period of each of the awards.

We selected the Black-Scholes-Merton, or Black-Scholes, option-pricing model as a fair value method for our options awards. The option-pricing model requires a number of assumptions:

Expected dividend yield - The expected dividend yield assumption is based on our historical experience and expectation of no future dividend payouts. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future.

Volatility - Since the Company’s shares started trading on a stock exchange market only in May 2013, quoted prices data of our shares is limited. According to ASC 718-10-30-20, in case of insufficient historical data for a company, the expected volatility was based on similar companies' stock volatility.

Risk free interest rate - The risk free interest rate is based on the yield of U.S. Treasury bonds with equivalent terms.

Expected term - ASC 718 provides the factors to consider when estimating the expected term of an option: An option’s expected term must at least include the vesting period and the Employees’ historical exercise and post-vesting employment termination behavior for similar grants. It also determines that if the amount of past exercise data is limited, that data may not represent a sufficiently large sample on which to base a robust conclusion on expected exercise behavior. In that circumstance, it may be appropriate to consider external data or the SEC staff’s “simplified” method for the expected term. Accordingly, we used the "simplified" method, meaning the expected life is set as the average of the vesting period for each vested tranche of options and the contractual term for those options.

Share price – Up until our initial public offering, because there had been no public market for our ordinary shares, the fair value of the ordinary shares underlying the options had been determined by our management, using the assistance of an independent valuation firm. Following our initial public offering, fair market value has been determined by NASDAQ Capital Market quotes.

Options granted during 2013 were mostly granted at the initial public offering price or the applicable closing price of our ordinary shares at the grant date.

We did not grant options to employees or directors in 2011 and 2012 (other than two grants as stated in Note 9(d) to the financial statements for the year ended December 31, 2013). For options granted up until December 31, 2010, the fair value of the ordinary shares was based on the application of Option-Pricing Method, or OPM. The first step in performing a valuation using OPM involves estimating the present value of the total shareholders' equity (preferred and Ordinary). As part of our analysis, we used recent investment rounds, respectively to the option valuation dates, in our shares in order to evaluate the present value of our total shareholders' equity.

Under the OPM, we estimated the fair value of the ordinary shares as the net value of a series of call options, representing the present value of the expected future returns to the shareholders. Essentially, the rights of the shareholders are equivalent to a call option on any value of the Company above the respective preferred shareholders' liquidation preferences, with adjustment to account for the rights retained by the preferred shareholders related to their share in any value above the values at which they would convert to ordinary shares. Thus, the ordinary shares were valued by estimating the value of their share in each of these call option rights.

Liquidity and Capital Resources

Overview

Since our inception through December 31, 2013, we have funded our operations principally with $63.2 million from the sale of ordinary shares, preferred shares and convertible notes. As of December 31, 2013, we had $22.1 million in cash and cash equivalents and an additional amount of $28 million in a short-term deposit.

	Years Ended December 31,		
	2013	**2012**	**2011**
	(in thousands of U.S. dollars)		
Operating activities	$ (7,353)	$ (1,583)	$ (2,361)
Investing activities	(28,047)	1,024	(1,041)
Financing activities	57,398	601	2,620
Net increase (decrease) in cash and cash equivalents	$ 21,998	$ 42	$ (782)

Operating Activities

Net cash used in operating activities of $7.3 million during the year ended December 31, 2013 was primarily used for payment of $5.6 million for clinical trials and other third party related expenses and for professional services, $0.2 million for travel expenses and an aggregate of $1.3 million in salary payments. The remaining amount of $0.2 million was for other miscellaneous expenses.

Net cash used in operating activities of $1.6 million during the year ended December 31, 2012 was primarily used for payment of $0.8 million for clinical trials and other third party expenses and an aggregate of $0.3 million in salary payments. The remaining amount of $0.5 million was for travel, rent and other miscellaneous expenses.

Net cash used in operating activities of $2.4 million during the year ended December 31, 2011 was primarily used for a payment of $1.6 million for clinical trials and other third party expenses and an aggregate of $0.4 million in salary payments. The remaining amount was for travel, rent and other miscellaneous expenses.

Investing Activities

Net cash used in investing activities of $28 million during 2013 reflected our use of cash to invest in short term deposits.

Net cash used in investing activities during 2011 was $1 million, which primarily reflected our use of cash to invest in short-term bank deposits, and an increase in restricted bank deposits. In 2012, we withdrew these deposits into cash.

Financing Activities

Net cash provided by financing activities of $57.3 million in the year ended December 31, 2013, consisted of a $21.9 million of proceeds from our initial public offering, $0.1 million of proceeds from issuance of convertible notes (that were converted into our ordinary shares at the time of our initial public offering), and $35.3 million of proceeds from a follow on public offering of our ordinary shares.

Net cash provided by financing activities in the year ended December 31, 2012 consisted of $0.6 million of net proceeds from issuance of convertible notes (that were converted into our ordinary shares at the time of our initial public offering). Net cash provided by financing activities in the year ended December 31, 2011 consisted of $2.1 million of net proceeds from issuance of ordinary shares, and $0.5 million of proceeds from loans.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our ordinary shares, loans and issuances of convertible notes. We have incurred losses and generated negative cash flows from operations since inception. To date, we have not generated any revenue from the sale of products and we do not expect to generate revenues from sale of our products in the next three years. Even if we are able to raise funds in the offering contemplated herein, we believe that we will need to raise additional funds before we have any cash flow from operations.

As of December 31, 2013, our cash, cash equivalents and short term deposits totaled $50.1 million. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus.

We believe that our existing cash resources will be sufficient to fund our projected cash requirements approximately through 2016 (such activities do not include conducting clinical trials in the EU or Japan). Nevertheless, we will require significant additional financing in the future to fund our operations if and when we obtain regulatory approval of MDX and commercialize the drug. We currently anticipate that we will utilize approximately $36 million for clinical trial activities over the course of the next 30 months. We also anticipate utilizing between $1 million to $6 million for capital expenditures over such 30-month period, which consists primarily of expenditures for the manufacture of our drug candidate for use in clinical trials and supporting pre-clinical studies required for obtaining approval to conduct such clinical studies. Our future capital requirements will depend on many factors, including:

- the progress and costs of our pre-clinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- any cost that we may incur under in- and out-licensing arrangements relating to our drug candidate that we may enter into in the future; the costs and timing of obtaining regulatory approval for our drug candidate;

- Ÿ the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

- Ÿ the costs of, and timing for, strengthening our manufacturing agreements for production of sufficient clinical and commercial quantities of our drug candidate;

- Ÿ the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally;

- Ÿ the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our drug candidate; the magnitude of our general and administrative expenses; and payments to the OCS. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through our existing cash, cash equivalents and short term deposits, the net proceeds from the current offering, debt or equity financings, or by out-licensing applications of our drug candidate. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our drug candidate.

5.E Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. Accordingly, a substantial majority of our cash and cash equivalents is held in deposits that bear interest. Given the current low rates of interest we receive, we will not be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail in the following paragraph.

5.F Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2013:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
			(in thousands of U.S. dollars)		
Operating leases:					
Facility	297	122	175	-	-
Motor Vehicles	111	48	63	-	-

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A. Directors and senior management

Executive Officers and Directors

The following table sets forth information regarding our executive officers, key employees and directors as of March 26, 2014:

Name	Age	Position
Howard B. Rosen	56	Chairman of the Board of Directors
Dr. Yaron Daniely	38	Chief Executive Officer, President and Director
Ehud (Udi) Gilboa (1)	47	Chief Financial Officer, Chief Accounting Officer and Director
Daniel E. Geffken (2) (3)	57	Director
Dr. Hadas Gelander (2) (3)	48	Director
Dr. Dalia Megiddo	62	Director
Ori Mor (2) (3)	43	Director
Dr. Aharon Schwartz	71	Director
Dr. Jonathan Rubin	52	Chief Medical Officer
David Baker	50	Chief Commercial Officer
Nir Peles	41	VP for Finance
Hanna Ron	63	SVP CMC
Dr. Johanna Schumann	33	VP for Preclinical Development
Aviva Galili Taiber	46	VP for Clinical Development

(1) The Company announced on February 19, 2014 that Mr. Gilboa step down as Chief Financial Officer and Chief Accounting Officer on May 1, 2014.

(2) Member of our Audit Committee.

(3) Member of our Compensation Committee.

Howard B. Rosen has served on our Board since the closing of our initial public offering in May 2013. Since 2008, Mr. Rosen has served as a consultant to several companies in the biotechnology industry. He has also served as a lecturer at Stanford University in Chemical Engineering since 2008 and in Management since 2011. Mr. Rosen served as interim President and Chief Executive Officer of Pearl Therapeutics, Inc., a company focused on developing combination therapies for the treatment of highly prevalent chronic respiratory diseases, from June 2010 to March 2011. From 2004 to 2008, Mr. Rosen was Vice President of Commercial Strategy at Gilead Sciences, Inc., a biopharmaceutical company. From 2003 until 2004, Mr. Rosen was President of ALZA Corporation, a pharmaceutical and medical systems company that merged with Johnson & Johnson, a global healthcare company, in 2001. Prior to that, from 1994 until 2003, Mr. Rosen held various positions at ALZA Corporation. Mr. Rosen is also a member of the board of directors of AcelRx Therapeutics, Inc. (Nasdaq: ACRX), a company developing products for pain relief, and a number of private biotechnology companies as follows: PaxVax, Inc., Entrega, Inc., Kala Pharmaceuticals, Inc. and ALDEA Pharmaceuticals. Previously, Mr. Rosen served on the board of directors of a number of public companies, as follows: Pharsight Corporation, a company focused on providing software products and consulting services to biopharmaceutical companies that was acquired by Tripos International in 2008 and CoTherix, Inc., a biopharmaceutical company that was acquired by Actelion Pharmaceuticals Ltd. in 2007. Mr. Rosen holds a B.S. in Chemical Engineering from Stanford University, an M.S. in Chemical Engineering from the Massachusetts Institute of Technology and an M.B.A. from the Stanford Graduate School of Business.

Dr. Yaron Daniely became our President and Chief Executive Officer and a Director in March 2010. Immediately prior to joining us and since 2007, Dr. Daniely was the President and Chief Executive Officer of NanoCyte, Inc., a company that develops transdermal delivery technologies based in Caesarea, Israel. Before NanoCyte and from 2004, Dr. Daniely was the General Manager of Gamida Cell—Teva Joint Venture Ltd., a joint venture company that acquired an exclusive license to develop and commercialize a Phase 3-stage cell therapy product for treatment of Leukemia and Lymphoma based in Jerusalem, Israel. From 2003-2007, Dr. Daniely also served as the Vice President of Business Development of Gamida Cell Ltd., and engaged in several licensing and financial transactions for the Company. In addition, he is a director of Bioblast Ltd, a private company incorporated in Israel. Dr. Daniely holds a B.Sc. degree in Biological Sciences from Florida International University, and holds a Ph.D. from the Sackler Institute of Graduate Biomedical Sciences at the New York University School of Medicine. Following his doctoral program, Dr. Daniely served as an NIH Visiting Fellow in its Cell Biology section and a Postdoctoral Fellow in the Department of Molecular Cell Biology at The Weizmann Institute for Science in Israel. Subsequently, he received an Executive M.B.A. from the Technion, Israel Institute of Technology.

Udi Gilboa co-founded the Company in February 2008, and became a director at that time. He has served as our Chief Financial Officer and Chief Accounting Officer since inception. Mr. Gilboa is the founder and managing partner of Top-Notch Capital, a prominent Israeli life sciences investment bank. He is also the founder of a number of medical device and pharmaceutical companies. Mr. Gilboa serves as a director of Insuline Medical Ltd. and served, until 2010, as a director and chairman of the board of directors of Topspin Medical Inc., two public companies whose shares are listed for trading on the Tel Aviv Stock Exchange. In addition, he is a director of Bio Blast Ltd. and Samson Neurosciences Ltd. Mr. Gilboa holds a Bachelor's degree and M.B.A. from Tel Aviv University.

Daniel E. Geffken has served on our Board of Directors and our Audit and Compensation Committees since our initial public offering in May 2013. Since October 2011, he has been Managing Director of Danforth Advisors, LLC, a management consulting firm that provides financial and strategic support to emerging life science companies. Mr. Geffken has also been the chief financial officer or chief operating officer of eight companies, four of which were U.S. public reporting companies and six of which were life science companies. He has a B.S. in Economics from The Wharton School, University of Pennsylvania, and a M.B.A. from Harvard Business School.

Dr. Hadas Gelander serves as one of our external directors, a member of our Audit Committee and the Chairperson of our Compensation Committee. Dr. Gelander currently serves as the Head of the Accounting Department at the College of Management, Academic Studies, School of Business Administration where she is also a professor. Dr. Gelander serves as an Independent Director on the Boards of EZ Energy (TASE: EZ), Eldav (TASE: ELDAV), Gindi Investments, Direct Capital, Tapuz, and Leumi Partners Underwriters, arm of Leumi Partners (merchant and investment banking arm of Leumi and Direct Capital). She is a member of the Council Committee for Interest Rate Organization as an accounting specialist. Dr. Gelander is a certified public accountant and since 2000 has served on the Israeli Council of Public Accountants , or CPA, where she is the Coordinator of Examinations of the Israeli CPA. Dr. Gelander earned her Ph.D. summa cum laude from Ben Gurion University, an MBA in Accounting and Finance from the Hebrew University of Jerusalem, and a Bachelor of Business degree from the College of Management Academic Studies.

Dr. Dalia Megiddo co-founded the Company in February 2008 and became a Director at that time. She is an entrepreneur and a medical doctor in family medicine. Since 2000, Dr. Megiddo has been a manager of InnoMed Ventures, an Israeli venture capital fund focused on life sciences. From 2006 to 2010, she was also a manager of 7 Health Ventures, an Israeli venture capital fund. Dr, Megiddo is also the founder of a number of life science companies. She is a director of Bioblast Ltd. and Humavox Ltd. and served as a director of Tulip Medical Ltd., Chiasma Inc. and Angioscore Inc. Dr. Megiddo received her M.D. degree from Hebrew University Hadassah Medical School and also holds an M.B.A. from the Kellogg-Recanati School of Business.

Ori Mor serves as one of our external directors, a member of our Compensation Committee and the Chairperson of our Audit Committee. Mr. Mor served as the CFO of Medical Compression Systems Ltd. (TASE: MDCL), a leader in innovative, non-invasive solutions for the prevention of venous thromboembolism (VTE), from 2009 to 2014, and is now CEO's advisor for corporate finance. Mr. Mor also serves as an External Director on the Boards of Birman Wood & Hardware Ltd. (TASE: BIRM) and as an external director and a chairperson of the investment committee of Excellence Nessuah Gemel & Pension Ltd. and as an Independent Director on the Board of Mordechai Aviv Taasiot Beniy Ltd. (TASE: AVIV). Mr. Mor previously served as CIO at Halman Aldubi and FIBI Provident Fund and has worked as a macro analyst at the provident funds of Bank Leumi and Mizrahi Bank. He holds an M.A. in Economics from Ben Gurion University.

Dr. Aharon Schwartz joined our Board as Chairman in January 2013, serving as our chairman until February 2014. He retired from Teva Pharmaceutical Industries Ltd where he served in a number of positions from 1957 through 2011, the most recent being Vice President, Head of Teva Innovative Ventures from 2008. He is also a member of the board of directors of Clal Biotechnology Industries Ltd. and the chairman of the board of directors of BioLineRx Ltd., BioCancell Therapeutics Inc., and several other biotechnology companies. He also serves as the chairman of Yissum Research Development Company of the Hebrew University of Jerusalem. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion Institute of Technology and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem.

Dr. Jonathan Rubin, M.D., M.B.A., serves as our Chief Medical Officer. He joined us in August 2013 after working at Shire Pharmaceuticals for more than six years, from 2007 through 2013, serving as a Medical Director in Global Medical Affairs supporting multiple products within the ADHD portfolio. As a Medical Director in Global Medical Affairs at Shire Pharmaceuticals, Dr. Rubin developed and implemented Global Medical Affairs strategic plans, planned and supervised medical launch activities in the United States and assisted with the design, execution and interpretation of Phase 2, 3 and Phase 4 studies. Dr. Rubin also served as the Director of Scientific Licensing Assessment at Shire Pharmaceuticals in 2011 where he identified and evaluated new opportunities for business development. Dr. Rubin began his pharmaceutical industry career as a medical consultant for Noven Pharmaceuticals in 2002. Until 2007 Dr. Rubin cared for children and adolescents with ADHD for 15 years at his General and Developmental-Behavioral Pediatric practice in Margate and Coconut Creek, Florida. He graduated with a B.S. from Yale University and an M.D. from the University of Connecticut, completed a pediatric residency at Albert Einstein/Montefiore, completed an Ambulatory Pediatric Fellowship at Boston Children’s Hospital and received an M.B.A. from Columbia Business School.

David Baker serves as our Chief Commercial Officer. He joined us in January 2014 after working at Shire Pharmaceuticals for ten years, most recently as Vice President of Commercial Strategy and New Business in the Neuroscience Business Unit. In this role he led the commercial assessment of neuroscience licensing opportunities, managed commercial efforts on pipeline CNS products, and led the long term strategic planning process. Previously, he served as Global General Manager for Vyvanse® where he led the launch of Vyvanse in 2007, oversaw the launch of the adult indication for Vyvanse in 2008, and led global expansion efforts to take Shire's ADHD portfolio beyond North America including successful establishment of a partnership in Japan and launches in Canada and Brazil. Prior to that, Mr. Baker served as Vice President of Marketing for all of Shire's ADHD products. Under his leadership, Adderall XR became the number one selling ADHD brand in the US. From 1990 - 2004, Mr. Baker worked at Merck where he held positions of increasing responsibility in marketing, sales, market research, and business development. In addition to his knowledge and experience with CNS medications, Mr. Baker's therapeutic expertise includes osteoporosis, migraine, and hyperlipidemia. He has been directly involved with the marketing of five leading prescription drugs with annual sales in excess of $1 billion each: Mevacor®, Zocor®, Fosamax®, Adderall XR, and Vyvanse.

Nir Peles became our Vice President for Finance in May 2013. Prior to joining us and since 2010, Mr. Peles was the CFO of BluePhoenix Solutions Ltd, (Nasdaq: BPHX), a leader in modernization of legacy technology using its proprietary automated software tools for translation and conversion of legacy applications and databases to modern platforms. Between the years 2007 and 2010, Mr. Peles served as a business development manager at Shiraz Investments, a privately-held investment company. Mr. Peles holds a B.A. in economics and accounting from the Hebrew University, an MBA from Tel Aviv University and an M.A. in law from Bar-Ilan University. Mr. Peles is a certified public accountant in Israel.

Hanna Ron serves as SVP CMC in the company. She has over 28 years of experience in the pharmaceutical industry and is an expert in chemistry, manufacturing and controls and pre-clinical studies. She has been providing full-time services to the Company since 2011 and has been a consultant to the pharmaceutical industry since 2009. From 2004 to 2009, she was the Vice President of Chemistry, Manufacturing and Controls at Bioline Innovations, an Israeli biotechnology company. She has held other positions in biotechnology and pharmaceutical companies, including being a chief research and development manager and a pharmaceutical product development manager at Teva Pharmaceuticals. Ms. Ron holds a B.Sc. in Pharmacy from Hebrew University in Jerusalem, an M.Sc. in Pharmaceutical Sciences (Clinical Pharmacy) from the Hebrew University and M.Sc. in Chemical Engineer from School of Engineering Tel Aviv University. She is licensed as a pharmacist, the Ministry of Health, Israel

Dr. Johanna Schumann, PhD, serves as our Vice President for Preclinical Development. She joined us in August 2013 after working at BioLineRx, an Israeli drug development company, from 2010 through 2013, serving as Preclinical Development Manager. In this role, she designed, managed and executed preclinical activities, including toxicology, pharmacokinetics and pharmacodynamics studies, in accordance with the relevant regulatory authorities' guidelines, for multiple preclinical phase drug development projects and medical indications. Dr Schumann holds a B.Sc. in Life Sciences from the Hebrew University of Jerusalem, and M.Sc. and Ph.D. in Pharmacology from the School of Pharmacy, The Hebrew University of Jerusalem.

Aviva Galili Taiber serves as our Vice President for clinical Development. She joined us in June 2010 after working at Icon clinical research, an international CRO, from 2003 through 2010, serving as regulatory expert and senior CRA. In these roles, she managed and executed clinical and regulatory activities, including set up, monitoring and management of clinical trials, submission to regulatory authorities (EC's and Ministry of Health), and supplying guidance on regulatory issues to the clinical team and sponsors. Ms. Taiber holds a BSc in Life Sciences from the Tel Aviv University and M.Sc. in epidemiology and preventive medicine from the School of medicine, Tel Aviv University.

6.B. Compensation

The aggregate amount of compensation paid or accrued to all of our directors and executive officers as a group with respect to the year ended December 31, 2013 was approximately $1.5 million. This amount includes salaries, consulting fees, directors' fees, car expenses and vacation, pension, severance, retirement or similar benefits or expenses, employer’s taxes, and bonus expenses in amount of $0.34 million. The amount does not include business travel, relocation, professional and business association due and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

In addition, stock based composition in the amount of $1.54 million was accrued in 2013.

Employment Agreement with Dr. Yaron Daniely

We entered into an employment agreement, dated March 4, 2010, with our Chief Executive Officer, Dr. Yaron Daniely. This employment agreement was amended several times, with the latest amendment approved by our shareholders on February 17, 2014. Under the terms of his amended employment agreement, Dr. Daniely is entitled to a gross monthly salary of $30,000. In addition, Dr. Daniely will be eligible to receive (i) a special bonus of $100,000 upon successful completion of Phase 3 Clinical Studies and (ii) an annual bonus in an amount of two to six monthly salaries, to be determined based on the achievement of certain milestones set by our Board of Directors. Dr. Daniely also received a special bonus of $200,000 in recognition of his efforts and contribution to consummate our initial public offering and a special bonus of $200,000 in recognition of his achievements in 2013. In addition, Dr. Daniely receives under the agreement other benefits that are provided for by Israeli law or that are customary for senior executives in Israel, including the right to use (and all related fixed and variable costs in respect of) a leased car and cellular telephone. Dr. Daniely is also entitled to company contributions equivalent to 5%, 8.33%, 2.5%, and 7.5% of his gross monthly salary towards certain pension, severance, disability and tax-advantaged savings funds respectively (known as a manager's insurance policy, severance compensation fund, disability insurance, and a study fund, respectively). Dr. Daniely also contributes 5% and 2.5% of his gross monthly salary towards the manager's insurance policy and study fund, respectively. Dr. Daniely’s employment engagement is terminable by either party upon sixty days prior written notice, and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. As required under Israeli law, the terms of Dr. Daniely’s engagement with our company have been approved by our Board of Directors and shareholders.

As of March 23, 2014, Dr. Daniely held options to purchase 580,013 ordinary shares under our 2010 Incentive Option Plan, of which 346,413 were vested.

Consulting Agreement with Dr. Dalia Megiddo

Dr. Dalia Megiddo has provided our company with consulting services related to pre-clinical, clinical, regulatory and intellectual property issues pursuant to an agreement, effective May 1, 2011 and terminable by either party upon 30 days’ prior written notice, with the latest amendment approved by our shareholders effective upon our initial public offering in May 2013. Under the terms of her amended agreement, the monthly amount payable to Dr. Megiddo is $5,000.

Services Agreement with Udi Gilboa

Udi Gilboa, our chief financial officer, has provided us with part time chief financial officer and chief operating officer services pursuant to a services agreement that became effective on March 1, 2008, with the latest amendment approved by our shareholders effective upon our initial public offering in May 2013. Under the terms of the amended services agreement, the monthly amount payable to Mr. Gilboa is $12,000, where the services agreement is terminable by either party upon 90 days' prior written notice. In addition, Mr. Gilboa received a special bonus of $50,000 in recognition of his efforts and contribution to consummate our initial public offering, and an additional bonus of $200,000 in recognition of his achievements in 2013.

Services of Dr. Aharon Schwartz as Director and Former Chairman of Our Board of Directors

Dr. Aharon Schwartz has served as a director and Chairman of the Board of Directors of our company since January 2, 2013. In February 2014, Dr. Schwartz resigned as our Chairman of the Board of Directors, and continues to serve as a director. In connection with such services, Dr. Schwartz receives a monthly amount of $3,333. In addition, we granted Dr. Schwartz 111,941 options to purchase ordinary shares under our 2010 Incentive Option Plan. Of such options, 89,553 shall vest according to our 2010 Incentive Option Plan, and the remaining 22,388 will vest subject to certain performance conditions.

Services of Daniel E. Geffken and Howard B. Rosen as Directors

Messrs. Geffken and Rosen have served as directors of our company since our initial public offering in May 2013. In connection with such services, each of Messrs. Geffken and Rosen are entitled to an annual amount of $30,000, payable quarterly at the end of each quarter. In addition, we granted each of Messrs. Geffken and Rosen 12,000 options to purchase ordinary shares under our 2010 Incentive Option Plan, such options to vest over a three year period.

Services of Dr. Hadas Gelander and Mr. Ori Mor as External Directors

Dr. Hadas Gelander and Mr. Ori Mor serve as our external directors. In connection with such services, they are each entitled to an annual amount of $30,000, payable quarterly at the end of the quarter, in addition to reimbursement of travel expenses.

We do not have written agreements with any director providing for benefits upon the termination of his employment with our company.

In December 2012, an amendment to the Companies Law, or Amendment 20, became effective, requiring companies to appoint a compensation committee. Our existing compensation committee as detailed in Item 6.C. "Board Practices. Board Committees. Compensation Committee" below meets this requirement.

Amendment 20 also requires us to adopt an office holder compensation policy no later than nine months from our initial public offering that will set forth company policy, or the Compensation Policy, regarding the terms of office and employment of office holders, including compensation, equity awards, severance and other benefits, exemption from liability and indemnification, referred to as the Terms of Office and Employment. The term "office holder," as defined in the Companies Law, includes directors, executive officers and any manager directly subordinate to the chief executive officer.

The Compensation Policy must be approved by the board of directors, after considering the recommendations of the compensation committee. The Compensation Policy must also be approved by a majority of the company's shareholders, provided that (i) such majority includes at least a majority of the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded), or (ii) the non-controlling shareholders and shareholders who do not have a personal interest in the matter who were present and voted against the policy hold two percent or less of the voting power of the company. The Compensation Policy must be approved by the board of directors and the shareholders every three years. If the Compensation Policy is not approved by the shareholders, the compensation committee and the board of directors may nonetheless approve the policy, following further discussion of the matter and for specified reasons.

Under Amendment 20, the Terms of Office and Employment of office holders require the approval of the compensation committee and the board of directors. The Terms of Office and Employment of directors and the chief executive officer must also be approved by shareholders.

Changes to existing Terms of Office and Employment of office holders (other than directors) can be made with the approval of the compensation committee only, if the committee determines that the change is not substantially different from the existing terms.

Under certain circumstances, the compensation committee and the board of directors may approve an arrangement that deviates from the Compensation Policy, provided that such arrangement is approved by the special majority of the company's shareholders mentioned above. Such shareholder approval will also be required with respect to determining the Terms of Office and Employment of a director or the chief executive officer during the transition period until the company adopts a Compensation Policy. Notwithstanding the foregoing, a company may be exempted from receiving shareholder approval with respect to the Terms of Office and Employment of a candidate for chief executive officer if such candidate meets certain independence criteria, the terms are in line with the Compensation Policy and the compensation committee has determined for specified reasons that shareholder approval would prevent the engagement.

Under the Companies Law and related regulations, the compensation payable to statutory independent directors and independent directors is subject to certain further limitations. See Item 6.C. "Board Practices. External Directors" below.

Our shareholders approved a Compensation Policy in February 2014 that meets the above requirements.

6.C. Board practices

Board of Directors

Under the Israeli Companies Law, setting up the Company's policy and oversight of our business is vested in our Board of Directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our Board of Directors, subject to the employment agreement that we have entered into with him. All other executive officers are appointed by our Chief Executive Officer, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association, our Board of Directors must consist of at least five and not more than eleven directors, including at least two external directors required to be appointed under the Israeli Companies Law. Accordingly, at any time, the minimum number of directors (other than the external directors) may not fall below three. Currently, our Board of Directors consists of eight directors, including two external directors. We have only one class of directors.

Other than external directors, for whom special election requirements and terms of office apply under the Israeli Companies Law as detailed below, our directors are each elected at a general meeting of our shareholders and serve for a term of roughly one year. Directors may nevertheless be removed prior to the end of their term by the majority of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, all in accordance with the Israeli Companies Law and our amended and restated articles of association.

In addition, our amended and restated articles of association allow our Board of Directors to appoint directors, other than external directors, to fill vacancies on our Board of Directors, for a term of office which shall continue until the next annual meeting following his or her appointment. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms (or more) under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Israeli Companies Law. See "—External Directors."

In accordance with the exemption available to foreign private issuers under NASDAQ rules, we do not follow the requirements of the NASDAQ rules with regard to the process of nominating directors, and instead, follow Israeli law and practice, in accordance with which our Board of Directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election. Under the Israeli Companies Law and our amended and restated articles of association, nominations for directors may also be added to the agenda of future general meetings, which has yet to have been summoned, upon the request of any shareholder holding at least one percent (1%) of our outstanding voting power. However, any such shareholder may make such a nomination only if a written notice of such shareholder's intent to make such nomination has been given to our chairman of the board (or, if we have no chairman of the board, our chief executive officer). Any such notice must include certain information we are required under the Israeli Companies Law to provide to our shareholders, the consent of the proposed director nominee(s) to serve as our director(s) if elected and a declaration signed by the nominee(s) declaring that there is no limitation under the Israeli Companies Law preventing their election and that all of the information that is required under the Israeli Companies Law to be provided to us in connection with such election has been provided.

In addition to its role in making director nominations, under the Israeli Companies Law, our Board of Directors must determine the minimum number of directors who are required to have accounting and financial expertise. Under applicable regulations, a director with accounting and financial expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements, sufficient to be able to thoroughly comprehend the financial statements of the Company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, our Board of Directors must consider, among other things, the type and size of our company and the scope and complexity of its operations. Our Board of Directors has determined that our company requires one director with such expertise. Mr. Mor has such accounting and financial expertise.

External Directors

Under the Israeli Companies Law, the boards of directors of companies whose shares are publicly traded, including companies with shares listed on the NASDAQ Capital Market, are required to include at least two members elected to serve as external directors. Accordingly, Mr. Mor and Dr. Gelander have been elected to serve as external directors.

The definitions of an external director under the Israeli Companies Law and independent director under NASDAQ listing rules are similar to such an extent that it would be generally expected that our two external directors will also comply with the independence requirement under the NASDAQ Stock Market rules. The definition of an external director includes a set of statutory criteria that must be satisfied, while the definition of an independent director also requires the board to consider any factor which would impair the ability of a director to exercise independent judgment. In addition, while external directors serve for a period of three years pursuant to the requirements of Israeli law, independent directors serve for one year pursuant to the provisions of our amended and restated articles of association. However, external directors must be elected by a special majority of shareholders while independent directors are elected by an ordinary majority.

The Israeli Companies Law provides that external directors must be elected by a majority vote of the shares present and voting at a shareholders meeting, provided that either:

- the majority voted in favor of election includes a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding for such purpose any abstentions, which we refer to as a disinterested majority; or

- the total number of shares held by non-controlling disinterested shareholders (as described in the previous bullet-point) that voted against the election of the director does not exceed two percent (2%) of the aggregate voting rights in the Company.

The term controlling shareholder is defined in the Israeli Companies Law as a shareholder with the ability to direct the activities of the Company, other than by virtue of being an office holder. A shareholder is in any case deemed to be a controlling shareholder if the shareholder holds 50% or more of the means of control, which include the right to vote at a shareholders meeting and the right to appoint the directors of the Company or its general manager. In connection with approval of certain extraordinary and interested party transactions as well as corporate approval of executive compensation, by shareholders, any shareholder (or group of shareholders having interest in the same matter being brought for approval) who hold(s) in the aggregate 25% or more of the means of control if no other shareholder holds more than 50% of the voting rights, would be deemed a controlling shareholder.

After an initial term of three years, external directors may be reelected to serve in that capacity for up to two additional three year terms, provided that either (i) (1) his or her service for each such additional term is recommended by one or more shareholders holding in aggregate at least one percent (1%) of the Company's voting rights and is approved at a shareholders meeting by a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding for such purpose any abstentions, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds two percent (2%) of the aggregate voting rights in the Company, and (2) the external director who has been nominated in such fashion by the shareholders is not a linked or competing shareholder, and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a material shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder(s) of the company's control, has a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine that certain matters will not constitute a business relationship or competition with the company; or (ii) his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same non-controlling and disinterested majority required for the initial election of an external director (as described above). The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Capital Market, may be further extended, indefinitely, in increments of additional three-year terms, in each case provided that, in addition to reelection in such manner described above, (i) the audit committee and subsequently the board of directors of the Company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period is beneficial to the Company, and (ii) prior to the approval of the reelection of the external director, the Company's shareholders have been informed of the term previously served by such nominee and of the reasons why the board of directors and audit committee recommended the extension of such nominee's term.

If an external directorship becomes vacant and there are less than two external directors on the board of directors at the time, then the board of directors is required under the Israeli Companies Law to call a shareholders' meeting as soon as possible to appoint a replacement external director.

Each committee of the board of directors that is authorized to exercise the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must each include all external directors then serving on the board of directors. Under the Israeli Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation for their services as external directors, other than compensation and reimbursement of expenses pursuant to applicable regulations promulgated under the Companies Law. Compensation of an external director is determined prior to his or her appointment and may not be changed during his or her term subject to certain exceptions.

The Israeli Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of the controlling shareholder of the Company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subject, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation or other prohibited relationship with the Company, with any person or entity who is a controlling shareholder of the Company at the date of appointment or a relative of such person, or with any entity controlled, during the two years preceding the date of appointment as an external director, by the Company or a controlling shareholder of the Company; or (b) in the case of a company with no controlling shareholder, any affiliation or other prohibited relationship with a person serving, at the date of appointment as external director, as chairman of the board, chief executive officer, a substantial shareholder or the most senior office holder in the Company's finance department.

The term relative is defined as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons. The term affiliation and the similar types of prohibited relationships include (subject to certain exemptions):

- Ÿ an employment relationship;
- Ÿ a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- Ÿ control; and
- Ÿ service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to be nominated to serve as an external director following the initial public offering.

The term office holder is defined under the Israeli Companies Law as the general manager (chief executive officer), chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director, or a manager directly subordinate to the general manager.

In addition, no person may serve as an external director if that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. A person may furthermore not continue to serve as an external director if he or she received direct or indirect compensation for his or her role as a director, other than compensation paid or given in accordance with Israeli Companies Law regulations or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage. Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided with direct or indirect benefit by the Company, its controlling shareholder or any entity under its controlling shareholder's control. This includes appointment as an office holder of the Company or a company controlled by its controlling shareholder, employment as an employee, or receipt of professional services for consideration, either directly or indirectly, including through a corporation in his or her control. These restrictions extend for a period of two years with regard to the former external director and his or her spouse or child, and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors, who are not controlling shareholders or relatives thereof, are of the same gender, the external director must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

According to the Israeli Companies Law, a person may be appointed as an external director only if he or she has professional qualifications or if he or she has accounting and financial expertise (each, as defined below). In addition, at least one of the external directors must be determined by our Board of Directors to have accounting and financial expertise. However, if at least one of our other directors (i) meets the independence requirements under the Exchange Act, (ii) meets the standards of the NASDAQ Listing Rules for membership on the audit committee, and (iii) has accounting and financial expertise as defined under Israeli law, then neither of our external directors is required to possess accounting and financial expertise as long as both possess other requisite professional qualifications.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, in such a manner which allows him or her to understand the financial statements of the Company and initiate a discussion about the presentation of financial data. A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public service, (ii) an academic degree or has completed other higher education, in the main field of business of the Company or a field relevant for the position, or (iii) at least five years of experience as one of the following, or at least five years accumulated experience as two or more of the following – (a) a senior officer in the business management of a company with a significant volume of business, (b) a senior public officer or senior position in the public service, and (c) a senior position in the Company's main line of business.

Our Board of Directors has determined that Mr. Mor possesses the requisite accounting and financial expertise and that Dr. Gelander possesses the requisite professional qualifications.

Leadership Structure of the Board

In accordance with the Israeli Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as Chairman of the Board of Directors. Our board of directors has appointed Mr. Howard Rosen to serve as Chairman of the Board of Directors.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the Board of Directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Board Committees

Audit Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board, any director employed by or otherwise providing services on a regular basis to the Company, to a controlling shareholder or to any entity controlled by a controlling shareholder, any director whose main livelihood is dependent on a controlling shareholder, nor a controlling shareholder or a relative thereof.

Under the Israeli Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors. An "unaffiliated director" is defined as either an external director or as a director, classified as an “unaffiliated director” by the Company, who meets the following criteria:

- Ÿ he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which in any event does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications, and the audit committee of the company confirmed such qualifications; and

- Ÿ he or she has not served as a director of the Company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Our Board of Directors has adopted an audit committee charter setting forth the responsibilities of the Audit Committee consistent with the rules of the SEC and the Listing Rules of the NASDAQ Stock Market, as well as the requirements for such committee under the Israeli Companies Law, as described below.

Our Audit Committee consists of Mr. Ori Mor, who serves as the chairperson of the committee, Mr. Geffken and Dr. Gelander.

Our Audit Committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our Audit Committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Israeli Companies Law, our Audit Committee is responsible for (i) determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the Board of Directors to improve such practices, (ii) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether such transaction should be deemed as material or extraordinary (according to certain criteria set by our Audit Committee on an annual basis) (see "—Approval of Related Party Transactions under Israeli Law"), (iii) where the Board of Directors approves the working plan of the internal auditor, to examine such working plan before its submission to the Board and propose amendments thereto, (iv) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities, (v) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our Board of Directors or shareholders, depending on which of them is considering the appointment of our auditor, and (vi) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees. In compliance with regulations promulgated under the Israeli Companies Law, our Audit Committee will also approve our financial statements, thereby fulfilling the requirement that a board committee provide such approval. Our Audit Committee may not approve an action or a related party transaction, or take any other action required under the Israeli Companies Law, unless at the time of approval a majority of the committee's members are present, which majority consists of unaffiliated directors including at least one external director, and it further complies with the committee composition set forth above.

NASDAQ requirements

Under the Nasdaq Marketplace Rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

As noted above, our audit committee consists of Dr. Gelander, Mr. Mor and Mr. Geffken. Mr. Mor is an audit committee financial expert as defined by the SEC rules and has the requisite financial sophistication as defined by the Nasdaq Marketplace Rules. All of the members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Listing Rules of the NASDAQ Stock Market.

Dr. Gelander, Mr. Mor and Mr. Geffken are independent as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and under the Listing Rules of the NASDAQ Stock Market.

Compensation Committee

We chose to rely upon the exemption available to foreign private issuers under the Listing Rules of the NASDAQ Stock Market with respect to the determination of the compensation of our Chief Executive Officer and other executive officers, and, in lieu of forming a compensation committee consisting entirely of independent directors (or the determination of such compensation solely by the independent members of our Board of Directors), we have a compensation committee in compliance with the Israeli Companies Law. See "—NASDAQ Listing Rules and Home Country Practices." However, all of the current members of our compensation committee are independent.

Under the Israeli Companies Law, the board of directors of a public company must appoint a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external directors, which shall be a majority of the members of the compensation committee and one of whom must serve as chairman of the committee. The rest of the members of the compensation committee shall be directors who do not receive direct or indirect compensation for their role as directors (other than compensation paid or given in accordance with Israeli Companies Law regulations applicable to the compensation of external directors, or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage).

The compensation committee may not include the chairman of the board, any director employed by or otherwise providing services on a regular basis to the Company, to a controlling shareholder or to any entity controlled by a controlling shareholder, any director whose main livelihood is dependent on a controlling shareholder, nor a controlling shareholder or a relative thereof.

Our Compensation Committee consists of Dr. Gelander, who serves as the chairperson of the committee, Mr. Geffken and Mr. Mor.

Under the Israeli Companies Law, our compensation committee is responsible for (i) proposing a Compensation Policy to the board of directors, (ii) propose necessary revisions to the Compensation Policy and examine its implementation, (iii) determining whether to approve transactions with respect to compensation of office holders, and (iv) determining, in accordance with our office holder compensation policy, whether to exempt an engagement with an unaffiliated nominee for the position of chief executive officer from requiring shareholders' approval.

Under the Israeli Companies Law, we are required to adopt an office holder compensation policy no later than nine months from our initial public offering.

NASDAQ Requirements

Dr. Gelander, Mr. Geffken and Mr. Mor. are independent under the listing standards of the NASDAQ Capital Market.

Nominating Committee

Our Board of Directors does not currently have a nominating committee, as director nominees are presented by our Board of Directors to our shareholders based upon the nominations made by the Board of Directors itself. We currently rely upon the exemption available to foreign private issuers under the Listing Rules of the NASDAQ Stock Market relating to independent director oversight of nominations to our Board of Directors and the adoption of a formal written charter or board resolution addressing the nominations process. See "—NASDAQ Listing Rules and Home Country Practices."

We do not have service contracts with any of our directors, except for Mr. Gilboa, Dr. Megiddo and Dr. Yaron Daniely. The remaining directors' compensation has been approved by our shareholders. Please see "Certain Relationships and Related Party Transactions—Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for a summary of these agreements.

Internal auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee and nominated by the board of directors. An internal auditor may not be:

- Ÿ a person (or a relative of a person) who holds more than 5% of the Company's outstanding shares or voting rights;
- Ÿ a person (or a relative of a person) who has the power to appoint a director or the general manager of the Company;
- Ÿ an office holder (including a director) of the Company (or a relative thereof); or
- Ÿ a member of the Company's independent accounting firm, or anyone on his or her behalf.

Guy Sapir, CPA, a partner at PWC Israel, was appointed as our internal auditor. The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures.

6.D. Employees

As of the date hereof we have nine employees. Our management consists of our Chief Executive Officer, our chief financial and accounting officer, our Chief Medical Officer, Chief Commercial Officer, SVP CMC (chemistry manufacturing and controls) & Non-clinical Development, our VP for Finance, VP for Preclinical Development as well as our VP for Clinical Development. We further have service agreements with U.S.-based regulatory consultants as well as additional U.S.-based clinical consultants who are members of our clinical advisory board. We believe that we maintain good relations with all of them.

6.E. Share ownership

As of March 1, 2014, each of our executive officers and directors, other than Mr. Gilboa, Dr. Megiddo and Dr. Daniely beneficially owned less than 1% of our Ordinary Shares.

2010 Incentive Option Plan

We maintain one equity incentive plan—our 2010 Incentive Option Plan, or our 2010 Plan. As of March 1, 2014, a total of 1,191,808 shares were reserved for issuance under our 2010 Plan, of which options to purchase 1,119,083 ordinary shares were issued and outstanding thereunder. Of such outstanding options, options to purchase 382,580 ordinary shares were vested as of March 1, 2014, with a weighted average exercise price of $3.12 per share.

Our 2010 Plan, which was adopted by our Board of Directors on February 3, 2010, provides for the grant of options to our and our affiliates' respective directors, employees, office holders, service providers and consultants.

The 2010 Plan is administered by our Board of Directors, which shall determine, subject to Israeli law, the grantees of awards and various terms of the grant. The 2010 Plan provides for granting options in compliance with Section 102 of the Israeli Income Tax Ordinance, 1961, or the Ordinance.

Options granted under the 2010 Plan to Israeli employees have been granted under the capital gains track of Section 102 of the Ordinance.

Section 102 of the Ordinance allows employees, directors and officers, who are not controlling shareholders and are considered Israeli residents, to receive favorable tax treatment for compensation in the form of shares or options. Our Israeli non-employee service providers and controlling shareholders may only be granted options under Section 3(9) of the Ordinance, which does not provide for similar tax benefits. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, the most favorable tax treatment for grantees, permits the issuance to a trustee under the "capital gains track." However, under this track we are not allowed to deduct an expense with respect to the issuance of the options or shares. In order to comply with the terms of the capital gains track, all options granted under the 2010 Plan pursuant and subject to the provisions of Section 102 of the Ordinance, as well as the ordinary shares issued upon exercise of these options and other shares received subsequently following any realization of rights with respect to such options, such as share dividends and share splits, must be granted to a trustee for the benefit of the relevant employee, director or officer and should be held by the trustee for at least two years after the date of the grant.

Options granted under the 2010 Plan will generally vest over four years commencing on the date of grant such that 25% vest after one year and an additional 6.25% vest at the end of each subsequent three-month period thereafter for 36 months. Options that are not exercised within ten years from the grant date expire, unless otherwise determined by the Board or its designated committee, as applicable. In case of termination for reasons of disability or death, the grantee or his legal successor may exercise options that have vested prior to termination within a period of six months from the date of disability or death. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested options will expire on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may exercise his or her vested options within 30 days of the date of termination. Any expired or unvested options return to the pool for reissuance.

In the event of a merger or consolidation of our company subsequent to which we shall no longer exist as a legal entity, or a sale of all, or substantially all, of our shares or assets or other transaction having a similar effect on us, then any outstanding option shall be assumed, or an equivalent option shall be substituted, by such successor corporation or an affiliate thereof or, in case the successor corporation refuses to assume or substitute the option, our Board of Directors or its designated committee may (a) provide the grantee with the opportunity to exercise the option as to all or part of the shares, vested or otherwise, and (b) specify a period of time, no less than seven days, following which all outstanding options shall terminate.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major shareholders

The following table sets forth information regarding the beneficial ownership by each person or entity known to beneficially own more than 5% of our ordinary shares as of March 1, 2014, or a different date, if so provided in the table below or footnotes thereof.

According to our transfer agent, as March 1, 2014, there were 20 record holders of our ordinary shares, among whom is one U.S. holder who beneficially owns less than 5% of our ordinary shares. None of our shareholders has different voting rights from other shareholders.

We are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is: c/o Alcobra Ltd., Amot Investment Building, 2 Weizman St. 9th Floor, Tel Aviv 6423902 Israel.

	Ordinary Shares Beneficially Owned	
Name	**Number**	**Percentage**
Udi Gilboa (1)	2,734,927	20%
Dr. Dalia Megiddo (1)	2,803,817	21%
Hadasit Medical Research Services & Development Ltd. (1)	776,192	6%
Knoll Capital Management (2)	687,000	5%
Austin W. Marxe, David M. Greenhouse and Adam C. Stettner (3)	661,401	5%

(1) Based solely on a Schedule 13G filed with the SEC on February 14, 2014, and which reflects holdings as of December 31, 2013.
(2) Based solely on an Amendment 1 to Schedule 13G filed with the SEC on February 14, 2014, and which reflects holdings as of December 31, 2013.
(3) Based solely on Amendment 1 to Schedule 13G filed with the SEC on February 6, 2014, and which reflects holdings as of December 31, 2013.

7.B. Related party transactions

For compensation to our directors and officers (See Item 6.B "Compensation").

Indemnification Agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by the Israeli Companies Law. We have entered into indemnification agreements with each of our directors and other office holders, undertaking to indemnify them to the fullest extent permitted by Israeli law. We have also obtained Directors & Officers insurance for each of our officers and directors. For further information, see "Management—Exculpation, Insurance and Indemnification of Directors and Officers."

7.C. Interests of experts and counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

8.A. Consolidated statements and other financial information

See Item 18 – Financial Statements.

Legal Proceedings

From time to time, we are involved in various routine legal proceedings incidental to the ordinary course of our business. We do not currently believe that the outcome of these legal proceedings have had in the recent past, or will have (with respect to any pending proceedings), significant effects on our financial position or profitability.

Dividends

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

The Israeli Companies Law imposes further restrictions on our ability to declare and pay dividends. See "Description of Share Capital—Dividend and Liquidation Rights" for additional information.

Payment of dividends may be subject to Israeli withholding taxes. See Item 10E below, "Taxation", for additional information.

8.B. Significant changes

Except as disclosed elsewhere in this annual report, there have been no other significant changes since December 31, 2013.

ITEM 9. THE OFFER AND LISTING

9.A. Offer and listing details

Our ordinary shares have been listed on the NASDAQ Capital Market under the symbol "ADHD" since May 22, 2013. Commencing on March 28, 2014, our ordinary shares will be listed on the NASDAQ Global Market. Prior to that date, there was no public trading market for our ordinary shares. Our initial public offering was priced at $8.00 per share on May 21, 2013. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on the NASDAQ Capital Market:

Annual Information:	**Low**	**High**
2013	**$ 6.64**	**$ 25.51**
Quarterly Information		
Second Quarter 2013	$ 6.64	$ 7.25
Third Quarter 2013	6.84	18.71
Fourth Quarter 2013	15.51	25.51
Monthly Information:		
September 2013	$ 12.47	$ 18.71
October 2013	15.68	25.51
November 2013	15.51	17.65
December 2013	16.43	18.49
January 2014	17.86	23.10
February 2014	19.95	25.02
March 2014 (through March 19, 2014)	20.10	23.61

9.B. Plan of distribution

Not applicable.

9.C. Market for Ordinary Shares

Our Ordinary Shares have been quoted on the Nasdaq Capital Market since May 22, 2013 under the symbol ADHD.

9.D. Selling shareholders

Not applicable**.**

9.E. Dilution

Not applicable**.**

9.F. Expenses of the issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share capital

Not applicable.

10.B. Memorandum and articles of association

Securities Register

We are registered with the Israeli Registrar of Companies. Our registration number is 51-409899-5. Section 2 of our articles of association provides that we may engage in any type of lawful business as may be determined by our board of directors from time to time.

Board of Directors

The Companies Law requires that certain transactions, actions and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the audit committee, the compensation committee, by the board of directors itself and by the shareholders. The vote required by the audit committee and the board of directors for approval of such matters, in each case, is a majority of the disinterested directors participating in a duly convened meeting. If, however, a majority of the members participating in such meeting have a personal interest in the approval of such matter, then all directors may participate in the discussions and the voting on approval thereof and in such case the matter shall be subject to further shareholder approval.

The Israeli Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may have concerning any existing or proposed transaction with the Company, as well as any substantial information or document with respect thereof. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of one's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the Company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of a relative of such office holder in a transaction that is not considered an extraordinary transaction. Under the Israeli Companies Law, an extraordinary transaction is defined as any of the following:

- Ÿ a transaction other than in the ordinary course of business;
- Ÿ a transaction that is not on market terms; or
- Ÿ a transaction that may have a material impact on a company's profitability, assets or liabilities.

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the Company's articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty. However, a company may not approve a transaction or action that is adverse to the Company's interest or that is not performed by the office holder in good faith. Approval first by the Company's audit committee and subsequently by the board of directors is required for an extraordinary transaction in which an office holder has a personal interest. Arrangements regarding the compensation, indemnification or insurance of an office holder require the approval of the compensation committee, board of directors and, in certain circumstances, the shareholders, in that order.

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a controlling shareholder or an officer who is a controlling shareholder of the Company, a controlling shareholder also includes any shareholder who holds 25% or more of the voting rights if no other shareholder holds more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be a single shareholder and may be deemed a controlling shareholder for the purpose of approving such transaction. Extraordinary transactions, including private placement transactions, with a controlling shareholder or in which a controlling shareholder has a personal interest, and engagements with a controlling shareholder or his or her relative, directly or indirectly, including through a corporation in his or her control, require the approval of the audit committee, the board of directors and the shareholders of the Company, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- Ÿ a disinterested majority; or
- Ÿ the votes of shareholders who have no personal interest in the transaction and who are present and voting, in person, by proxy or by voting deed at the meeting, and who vote against the transaction may not represent more than two percent (2%) of the voting rights of the Company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the terms of engagement and compensation of a controlling shareholder who is an office holder, and the terms of employment of a controlling shareholder who is an employee of the Company, require the approval of the compensation committee, board of directors and, generally, the shareholders, in that order.

Our articles of association provide that, all actions done bona fide at any meeting of the board of directors or by a committee thereof or by any person(s) acting as director(s) will, notwithstanding that it may afterwards be discovered that there was some defect in the appointment of the participants in such meeting or any of them or any person(s) acting as aforesaid, or that they or any of them were disqualified, be as valid as if there were no such defector disqualification.

- Our articles of association provide that a director who has a personal interest in an extraordinary transaction which is brought for discussion before our board of directors or our audit committee shall neither vote in nor attend discussions concerning the approval of such transaction. If the director did vote or attend as aforesaid, the approval given to the aforesaid activity or arrangement will be invalid.

- Our articles of association provide that, subject to the Companies Law, our board of directors may delegate its authority, in whole or in part, to such committees of the board of directors as it deems appropriate, and it may from time to time revoke such delegation. To the extent permitted by the Companies Law, our board of directors may from time to time confer upon and delegate to a President, Chief Executive Officer, Chief Operating Officer or other executive officer then holding office, such authorities and duties of the board of directors as it deems fit, and they may delegate such authorities and duties for such period and for such purposes and subject to such conditions and restrictions which they consider in our best interests, without waiving the authorities of the board of directors with respect thereto.

- Arrangements regarding compensation of directors require the approval of the compensation committee, audit committee, our board of directors and the shareholders.

Rights, Preferences and Restrictions of Shares

- General. Our share capital is NIS 500,000, divided into 50,000,000 Ordinary shares NIS 0.01 par value per share.

- The Ordinary Shares do not have cumulative voting rights in the election of directors. As a result, the holders of Ordinary Shares that represent more than 50% of the voting power have the power to elect all the Directors.

- Dividend and liquidation rights. Our board of directors may declare a dividend to be paid to the holders of our Ordinary Shares according to their rights and interests in our profits and may fix the record date for eligibility and the time for payment. The directors may from time to time pay to the shareholders on account of the next forthcoming dividend such interim dividends as, in their judgment, our position justifies. All dividends unclaimed for one year after having been declared may be invested or otherwise used by the directors for our benefit until claimed. No unpaid dividend or interest shall bear interest as against us. Our board of directors may determine that a dividend may be paid, wholly or partially, by the distribution of certain of our assets or by a distribution of paid up shares, debentures or debenture stock or any of our securities or of any other companies or in any one or more of such ways in the manner and to the extent permitted by the Companies Law.

- Transfer of shares; record dates. Fully paid up Ordinary Shares may be freely transferred pursuant to our amended and restated articles of association unless such transfer is restricted or prohibited by another instrument or securities laws. Each shareholder who would be entitled to attend and vote at a General Meeting of shareholders is entitled to receive notice of any such meeting. For purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors will fix a record date.

- Voting; annual general and extraordinary meetings. Subject to any rights or restrictions for the time being attached to any class or classes of shares, each shareholder shall have one vote for each share of which he or she is the holder, whether on a show of hands or on a poll. Our articles of association do not permit cumulative voting and it is not mandated by Israeli law. Votes may be given either personally or by proxy. A proxy need not be a shareholder. If any shareholder is without legal capacity, he may vote by means of a trustee or a legal custodian, who may vote either personally or by proxy. If two or more persons are jointly entitled to a share then, in voting upon any question, the vote of the senior person who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other registered holders of the share and, for this purpose seniority shall be determined by the order in which the names stand in the shareholder register.

- Quorum for general meetings.The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who holds or represent between them at least one-third of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time/date if so specified in the summons or notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

- Notice of general meetings. Unless a longer period for notice is prescribed by the Companies Law, at least 10 days and not more than 60 days' notice of any general meeting shall be given, specifying the place, the day and the hour of the meeting and, in the case of special business, the nature of such business, shall be given in the manner hereinafter mentioned, to such shareholders as are under the provisions of our articles of association, entitled to receive notices from us. Only shareholders of record as reflected on our share register at the close of business on the date fixed by the board of directors as the record date determining the then shareholders who will be entitled to vote, shall be entitled to notice of, and to vote, in person or by proxy, at a general meeting and any postponement or adjournment thereof.

- Annual; agenda; calling a general meeting. General Meetings are held at least once in every calendar year at such time (within a period of 15 months after the holding of the last preceding General Meeting), and at such time and place as may be determined by the board of directors. At a General Meeting, decisions shall be adopted only on matters that were specified on the agenda. The board of directors is obligated to call extraordinary general meeting of the shareholders upon a written request in accordance with the Companies Law. The Companies Law provides that an extraordinary general meeting of shareholder may be called by the board of directors or by a request of two directors or 25% of the directors in office, or by shareholders holding at least 5% of the issued share capital of the company and at least 1% of the voting rights, or of shareholders holding at least 5% of the voting rights of the company.

- Majority vote. Except as otherwise provided in the articles of association, any resolution at a General Meeting shall be deemed adopted if approved by the holders of a majority of our voting rights represented at the meeting in person or by proxy and voting thereon. In the case of an equality of votes, the chairman of the meeting shall not be entitled to a further vote.

- Discrimination against shareholders. According to our articles of association, there are no discriminating provisions against any existing or prospective holders of our shares as a result of a shareholder holding a substantial number of shares.

Modification of Class Rights

If, at any time, the share capital is divided into different classes of shares, the rights attached to any class (unless otherwise provided by the terms of issuance of the shares of that class) may be varied with the consent in writing of the holders of all the issued shares of that class, or with the sanction of a majority vote at a meeting of the shareholders passed at a separate meeting of the holders of the shares of the class. The provisions of our articles of association relating to general meetings shall apply, mutatis mutandis, to every such separate general meeting. Any holder of shares of the class present in person or by proxy may demand a secret poll.

Unless otherwise provided by the conditions of issuance, the enlargement of an existing class of shares, or the issuance of additional shares thereof, shall not be deemed to modify or abrogate the rights attached to the previously issued shares of such class or of any other class. These conditions provide for the minimum shareholder approvals permitted by the Companies Law.

Restrictions on Shareholders Rights to Own Securities

Our articles of association and the laws of the State of Israel do not restrict in any way the ownership or voting or our shares by non-residents of Israel, except with respect to subjects of countries which are in a state of war with Israel.

Acquisitions under Israeli Law

Full tender offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special tender offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder of control in the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer.

In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them shall refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control of the other party to the merger or any one on their behalf including their relatives or corporations controlled by any of them, vote against the merger.

If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Potential Issues that Could Delay a Merger

Our articles of association provides for a staggered board of directors, which could delay, defer or prevent a change of control. In addition, certain provisions of Israeli corporate and tax law may have the effect of delaying, preventing or making more difficult any merger or acquisition of us. For example, any merger or acquisition of us will require the prior consent of the Chief Scientist, as well as the Investment Center. See Item 3.D – Risk factors "We are subject to anti-takeover provisions that could delay or prevent our acquisition by another entity."

Requirement of Disclosure of Shareholder Ownership

There are no provisions of our memorandum of association or articles of association governing the ownership threshold above which shareholder ownership must be disclosed. We are subject, however, to U.S. securities rules that require beneficial owners of more than 5% of our ordinary Shares to make certain filings with the SEC.

Changes in Capital

Our memorandum of association and articles of association do not impose any conditions governing changes in capital that are more stringent than required by the Companies Law.

10.C. Material contracts

For agreements with our officers and directors see Item 6.B. – "Compensation."

10.D. Exchange controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Non-residents of Israel who purchase our securities with non-Israeli currency will be able to repatriate dividends (if any), liquidation distributions and the proceeds of any sale of such securities, into non-Israeli currencies at the rate of exchange prevailing at the time of repatriation, provided that any applicable Israeli taxes have been paid (or withheld) on such amounts.

Neither our articles of association nor the laws of the State of Israel restrict in any way the ownership or voting of ordinary shares by non-residents of Israel, except with respect to citizens of countries that are in a state of war with Israel.

10.E. Taxation

The following is a summary of the current tax structure, which is applicable to companies in Israel, with special reference to its effect on us. The following also contains a discussion of material Israeli and U.S. tax consequences to persons purchasing our Ordinary Shares and government programs from which we and some of our group companies benefit. To the extent that the discussion is based on new tax legislation, which has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed in the discussion will accord with any such interpretation in the future. The discussion is not intended and should not be construed as legal or professional tax advice and is not exhaustive of all possible tax considerations. An Israeli company that is subject to Israeli taxes on the income of its non-Israeli subsidiaries will receive a credit for income taxes paid/withheld or that will be paid/withheld by the subsidiary in its country of residence, according to the terms and conditions determined in the Israeli Tax Ordinance.

The following summary is included herein as general information only and is not intended as a substitute for careful tax planning. Accordingly, each investor should consult his or her own tax advisor as to the particular tax consequences to such investor of the purchase, ownership or sale of an ordinary share, including the effect of applicable state, local, foreign or other tax laws and possible changes in tax laws.

Israeli Taxation Considerations

The following is a summary of the material Israeli income tax laws applicable to us. This section also contains a discussion of material Israeli income tax consequences concerning the ownership and disposition of our ordinary shares. This summary does not discuss all the aspects of Israeli income tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. This summary is based on laws and regulations in effect as of the date of this prospectus and does not take into account possible future amendments which may be under consideration.

General corporate tax structure in Israel

Israeli resident companies, such as the Company, are generally subject to corporate tax at the rate of 26.5%.

Capital gains derived by an Israeli resident company are generally subject to tax at the same rate as the corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an “Israeli Resident” if it meets one of the following: (a) it was incorporated in Israel; or (b) the control and management of its business are exercised in Israel.

Taxation of our Israeli individual shareholders on receipt of dividends

Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of 25%, or 30% if the recipient of such dividend is a "substantial shareholder” (as defined below) at the time of distribution or at any time during the preceding 12-month period.

As of January 1, 2013, an additional income tax at a rate of 2% will be imposed on high earners whose annual income or gain exceeds NIS 811,560.

A “substantial Shareholder” is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the “means of control” of the corporation. “Means of control” generally include the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

The term “Israeli Resident” is generally defined under Israeli tax legislation with respect to individuals as a person whose center of life is in Israel. The Israeli Tax Ordinance New Version, 1961 (as amended by Amendment Law No. 132 of 2002) (the “Israeli Tax Ordinance”) determines that in order to determine the center of life of an individual, account will be taken of the individual’s family, economic and social connections, including: (a) place of permanent home; (b) place of residential dwelling of the individual and the individual’s immediate family; (c) place of the individual’s regular or permanent occupation or the place of his permanent employment; (d) place of the individual’s active and substantial economic interests; (e) place of the individual’s activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (a) the individual was present in Israel for 183 days or more in the tax year; or (b) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual’s presence in Israel in that tax year and the two previous tax years is 425 days or more. The presumption in this paragraph may be rebutted either by the individual or by the assessing officer.

Taxation of Israeli Resident Corporations on Receipt of Dividends

Israeli resident corporations are generally exempt from Israeli corporate income tax with respect to dividends paid on our ordinary shares.

Capital Gains Taxes Applicable to Israeli Resident Shareholders

The income tax rate applicable to Real Capital Gain derived by an Israeli individual from the sale of shares which had been purchased after January 1, 2012, whether listed on a stock exchange or not, is 25%. However, if such shareholder is considered a “Substantial Shareholder” (as defined above) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. As of January 1, 2013, an additional tax at a rate of 2% will be imposed on high earners whose annual income or gains exceed NIS 811,560.

Moreover, capital gains derived by a shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income, are taxed in Israel at ordinary income rates (currently, 26.5% for corporations and up to 50% for individuals).

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our Shares at the rate of 25% (or 30% for individuals, if such person is a “substantial shareholder” at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at source, unless a lower tax rate is provided in a tax treaty between Israel and the shareholder’s country of residence.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the duty to file returns in Israel in respect of such income; provided such income was not derived from a business conducted in Israel by the taxpayer, and the taxpayer has no other taxable sources of income in Israel.

For example, under the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended (the "U.S.-Israel Tax Treaty"), Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%, or 15% in the case of dividends paid out of the profits of a Benefited Enterprise, subject to certain conditions. Where the recipient is a U.S. corporation owning 10% or more of the voting shares of the paying corporation during the part of the paying corporation’s taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any) and the dividend is not paid from the profits of a Benefited Enterprise, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

Capital gains income taxes applicable to non-Israeli shareholders.

Non-Israeli resident shareholders are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemptions if an Israeli resident (i) has a controlling interest of more than 25% in such non-Israeli corporation or (ii) is the beneficiary of or is entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

Regardless of whether shareholders may be liable for Israeli income tax on the sale of our ordinary shares, the payment of the consideration may be subject to withholding of Israeli tax at the source. Accordingly, shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

United States Federal Income Tax Consequences

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ORDINARY SHARES, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

U.S. Federal Income Taxation

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership and sale of the Ordinary Shares. For this purpose, a "U.S. Holder" is a holder of Ordinary Shares that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury Regulations) created or organized in or under the laws of the United States or the District of Columbia or any political subdivision thereof; (3) an estate, the income of which is subject to U.S. federal income tax regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations; or (6) any person otherwise subject to U.S. federal income tax on a net income basis in respect of the Ordinary Shares, if such status as a U.S. Holder is not overridden pursuant to the provisions of an applicable tax treaty.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase or hold our Ordinary Shares. This summary generally considers only U.S. Holders that will own our Ordinary Shares as capital assets. Except to the limited extent discussed below, this summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended, or the Code, final, temporary and proposed U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof, and the U.S./Israel Income Tax Treaty, all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. The Company will not seek a ruling from the U.S. Internal Revenue Service, or the IRS, with regard to the U.S. federal income tax treatment of an investment in our Ordinary Shares by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the aspects of U.S. federal income taxation that may be relevant to a particular shareholder based on such shareholder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity"; (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our Ordinary Shares in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our Ordinary Shares as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity; (7) real estate investment trusts; (8) a U.S. Holder that expatriates out of the United States or a former long-term resident of the United States; or (9) a person having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, Ordinary Shares representing 10% or more of our voting power. Additionally, the U.S. federal income tax treatment of persons who hold Ordinary Shares through a partnership or other pass-through entity are not considered.

You are encouraged to consult your own tax advisor with respect to the specific U.S. federal and state income tax consequences to you of purchasing, holding or disposing of our Ordinary Shares, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Distributions on Ordinary Shares

Subject to the discussion under the heading "Passive Foreign Investment Companies" below, a U.S. Holder will be required to include in gross income as ordinary income the amount of any distribution paid on Ordinary Shares (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the Ordinary Shares to the extent thereof, and then capital gain. Corporate holders generally will not be allowed a deduction for dividends received. For noncorporate U.S. Holders, to the extent that their total adjusted income does not exceed applicable thresholds, the maximum federal income tax rate for "qualified dividend income" and long-term capital gains is generally 15%. For those noncorporate U.S. Holders whose total adjusted income exceeds such income thresholds, the maximum federal income tax rate for "qualified dividend income" and long-term capital gains is generally 20%. For this purpose, "qualified dividend income" means, *inter alia*, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program. The IRS has stated that the Israel/U.S. Tax Treaty satisfies this requirement and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our Ordinary Shares are readily tradable on NASDAQ or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a passive foreign investment company, or PFIC. A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our Ordinary Shares or ADRs for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our Ordinary Shares are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our Ordinary Shares will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Israeli taxes withheld therefrom. (See discussion above under "Israeli Taxation Considerations - Taxation of Our Shareholders – Dividends.") Cash distributions paid by us in NIS will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the NIS, any subsequent gain or loss in respect of such NIS arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

Distributions paid by us will generally be foreign source income for U.S. foreign tax credit purposes. Subject to the limitations set forth in the Code, U.S. Holders may elect to claim a foreign tax credit against their U.S. income tax liability for Israeli income tax withheld from distributions received in respect of the Ordinary Shares. In general, these rules limit the amount allowable as a foreign tax credit in any year to the amount of regular U.S. tax for the year attributable to foreign source taxable income. This limitation on the use of foreign tax credits generally will not apply to an electing individual U.S. Holder whose creditable foreign taxes during the year do not exceed $300, or $600 for joint filers, if such individual's gross income for the taxable year from non-U.S. sources consists solely of certain passive income. A U.S. Holder will be denied a foreign tax credit with respect to Israeli income tax withheld from dividends received with respect to the Ordinary Shares if such U.S. Holder has not held the Ordinary Shares for at least 16 days out of the 31-day period beginning on the date that is 15 days before the ex-dividend date or to the extent that such U.S. Holder is under an obligation to make certain related payments with respect to substantially similar or related property. Any day during which a U.S. Holder has substantially diminished his or her risk of loss with respect to the Ordinary Shares will not count toward meeting the 16-day holding period. A U.S. Holder will also be denied a foreign tax credit if the U.S. Holder holds the Ordinary Shares in an arrangement in which the U.S. Holder's reasonably expected economic profit is insubstantial compared to the foreign taxes expected to be paid or accrued. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult with their own tax advisors to determine whether, and to what extent, they are entitled to such credit. U.S. Holders that do not elect to claim a foreign tax credit may instead claim a deduction for Israeli income taxes withheld, provided such U.S. Holders itemize their deductions.

Disposition of Shares

Except as provided under the PFIC rules described below, upon the sale, exchange or other disposition of our Ordinary Shares, a U.S. Holder will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis in the sold Ordinary Shares and the amount realized on the disposition of such Ordinary Shares (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale or exchange or other disposition of Ordinary Shares will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition.

In general, gain realized by a U.S. Holder on a sale, exchange or other disposition of Ordinary Shares will generally be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. Holder on the sale, exchange or other disposition of Ordinary Shares is generally allocated to U.S. source income. However, U.S. Treasury Regulations require such loss to be allocated to foreign source income to the extent specified dividends were received by the taxpayer within the 24-month period preceding the date on which the taxpayer recognized the loss. The deductibility of a loss realized on the sale, exchange or other disposition of Ordinary Shares is subject to limitations.

Tax on Net Investment Income

U.S. Holders who are individuals, estates or trusts will generally be required to pay a new 3.8% tax on their net investment income (including dividends on and gains from the sale or other disposition of our Ordinary Shares), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to a U.S. Holder who owns shares of a corporation that was (at any time during the U.S. Holder's holding period) a PFIC. We would be treated as a PFIC for U.S. federal income tax purposes for any tax year if, in such tax year, either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, U.S. or foreign, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive (the "Income Test"); or

- At least 50% of our assets, averaged over the year and generally determined based upon value (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value), in a taxable year are held for the production of, or produce, passive income (the "Asset Test").

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

If we are or become a PFIC, each U.S. Holder who has not elected to treat us as a qualified electing fund by making a "QEF election", or who has not elected to mark the shares to market (as discussed below), would, upon receipt of certain distributions by us and upon disposition of our Ordinary Shares at a gain, be liable to pay U.S. federal income tax at the then prevailing highest tax rates on ordinary income plus interest on such tax, as if the distribution or gain had been recognized ratably over the taxpayer's holding period for the Ordinary Shares. In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to special U.S. federal income tax rules.

The PFIC rules would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the Ordinary Shares while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's *pro rata* share of our ordinary earnings as ordinary income and such U.S. Holder's *pro rata* share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. In general, a QEF election is effective only if we make available certain required information. The QEF election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS. U.S. Holders should consult with their own tax advisors regarding eligibility, manner and advisability of making a QEF election if we are treated as a PFIC.

A U.S. Holder of PFIC shares which are traded on qualifying public markets, including the NASDAQ, can elect to mark the shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the PFIC shares and the U.S. Holder's adjusted tax basis in the PFIC shares. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years.

Based on the value of our assets and the composition of our assets and income, it is unlikely that we were a “passive foreign investment company,” or PFIC, for U.S. federal income tax purposes for our taxable year ended December 31, 2013. In light of the complexity of PFIC rules, we cannot assure you that we have not been a PFIC in prior years or are not a PFIC or will avoid becoming a PFIC in the future. U.S. Holders who hold Ordinary Shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC, subject to specified exceptions for U.S. Holders who made a QEF or mark-to-market election. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to our Ordinary Shares in the event we that qualify as a PFIC.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding (at a rate of 28%) with respect to cash dividends and proceeds from a disposition of Ordinary Shares. In general, back-up withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

Under the Hiring Incentives to Restore Employment Act of 2010 (the "HIRE Act"), some payments made to "foreign financial institutions" in respect of accounts of U.S. stockholders at such financial institutions may be subject to withholding at a rate of 30%. U.S. Treasury Regulations provide that such withholding will only apply to distributions paid on or after January 1, 2014, and to other "withholdable payments" (including payments of gross proceeds from a sale or other disposition of our Ordinary Shares) made on or after January 1, 2017. U.S. Holders should consult their tax advisors regarding the effect, if any, of the HIRE Act on their ownership and disposition of our Ordinary Shares. See "Non-U.S. Holders of Ordinary Shares."

Non-U.S. Holders of Ordinary Shares

Except as provided below, an individual, corporation, estate or trust that is not a U.S. Holder generally will not be subject to U.S. federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, our Ordinary Shares.

A non-U.S. Holder may be subject to U.S. federal income or withholding tax on a dividend paid on our Ordinary Shares or the proceeds from the disposition of our Ordinary Shares if: (1) such item is effectively connected with the conduct by the non-U.S. Holder of a trade or business in the United States or, in the case of a non-U.S. Holder that is a resident of a country which has an income tax treaty with the United States, such item is attributable to a permanent establishment or, in the case of gain realized by an individual non-U.S. Holder, a fixed place of business in the United States; (2) in the case of a disposition of our Ordinary Shares, the individual non-U.S. Holder is present in the United States for 183 days or more in the taxable year of the sale and other specified conditions are met; (3) the non-U.S. Holder is subject to U.S. federal income tax pursuant to the provisions of the U.S. tax law applicable to U.S. expatriates.

In general, non-U.S. Holders will not be subject to backup withholding with respect to the payment of dividends on our Ordinary Shares if payment is made through a paying agent, or office of a foreign broker outside the United States. However, if payment is made in the United States or by a U.S. related person, non-U.S. Holders may be subject to backup withholding, unless the non-U.S. Holder provides on an applicable Form W-8 (or a substantially similar form) a taxpayer identification number, certifies to its foreign status, or otherwise establishes an exemption. A U.S. related person for these purposes is a person with one or more current relationships with the United States.

The amount of any backup withholding from a payment to a non-U.S. Holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

The HIRE Act may impose withholding taxes on some types of payments made to "foreign financial institutions" and some other non-U.S. entities. Under the HIRE Act, the failure to comply with additional certification, information reporting and other specified requirements could result in withholding tax being imposed on payments of dividends and sales proceeds to U.S. Holders that own Ordinary Shares through foreign accounts or foreign intermediaries and specified non-U.S. Holders. The HIRE Act imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, Ordinary Shares paid from the United States to a foreign financial institution or to a foreign nonfinancial entity, unless (1) the foreign financial institution undertakes specified diligence and reporting obligations or (2) the foreign nonfinancial entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. In addition, if the payee is a foreign financial institution, it generally must enter into an agreement with the U.S. Treasury that requires, among other things, that it undertake to identify accounts held by specified U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to other specified account holders. U.S. Treasury Regulations provide that such withholding will only apply to distributions paid on or after January 1, 2014, and to other "withholdable payments" (including payments of gross proceeds from a sale or other disposition of our Ordinary Shares) made on or after January 1, 2017. You should consult your tax advisor regarding the HIRE Act.

10.F. Dividends and paying agents

Not applicable.

10.G. Statement by experts

Not applicable.

10.H. Documents on display

We are subject to certain of the information reporting requirements of the Exchange Act, or the Exchange Act. As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing 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, with respect to their purchase and sale of our shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

You may read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, 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, NE, Washington, D.C. 20549. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of this website is http://www.sec.gov. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

10.I. Subsidiary information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. Accordingly, a substantial majority of our cash and cash equivalents is held in deposits that bear interest. Given the current low rates of interest we receive, we will not be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail in the following paragraph.

Foreign Currency Exchange Risk

Our results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. As discussed above, the vast majority of our liquid assets is held in U.S. dollars, and a certain portion of our expenses is denominated in NIS. For instance, in 2013, approximately 12% of our expenses were denominated in NIS. Changes of 5% and 10% in the $/NIS exchange rate would have increased/decreased the operation expenses by 2% and 4%, respectively. However, these historical figures may not be indicative of future exposure, as we expect that the percentage of our NIS denominated expenses will materially decrease in the near future, therefore reducing our exposure to exchange rate fluctuations.

We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

The Company does not have any outstanding American Depositary Shares or American Depositary Receipts.

PART TWO

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

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

None.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2013, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

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

This annual report does not include a report of management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the Company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2013, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM1 6A. Audit Committee Financial Expert

Our board of directors has determined that Mr. Mor, a member of our audit committee, is an audit committee financial expert, as defined under the rules under the Exchange Act, and is independent in accordance with applicable Exchange Act rules and Nasdaq rules.

ITEM 16B. Code of Ethics

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at www.alcobra-pharma.com.

ITEM 16C. Principal Accountant Fees and Services

Kost Forer Gabbay & Kasierer (a Member of Ernst & Young Global), has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2013 and 2012.

The following table provides information regarding fees paid by us to Kost Forer Gabbay & Kasierer and/or other member firms of Ernst & Young Global for all services, including audit services, for the years ended December 31, 2013 and 2012:

	Year Ended December 31,	
	2013	2012
Audit fees [1]	$ 67	$ 80
Audit-related fees [2]	75	220
Tax fees [3]	23	8
Total	$ 165	$ 308

(1) Includes professional services rendered in connection with the audit of our annual financial statements and the review of our interim financial statements.
(2) Includes fees for the IPO and secondary offering.
(3) Includes professional fees related to tax returns, transfer pricing and consulting on state and sales tax in the United States.

Pre-Approval of Auditors' Compensation

Our audit committee is responsible for pre-approving audit and non-audit services provided to us by our independent registered public accounting firm. All of the non-audit services provided to us by the independent auditors in 2013 were 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

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, require foreign private issuers, such as us, to comply with various corporate governance practices. In addition, following the listing of our ordinary shares on the NASDAQ Capital Market, we are required to comply with the Listing Rules of the NASDAQ Stock Market. Under those Listing Rules, we may elect to follow certain corporate governance practices permitted under the Israeli Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Listing Rules of the NASDAQ Stock Market for U.S. domestic issuers.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the Listing Rules of the NASDAQ Stock Market, we have elected to follow the provisions of the Israeli Companies Law, rather than the Listing Rules of the NASDAQ Stock Market, with respect to the following requirements:

- Ÿ *Distribution of periodic reports to shareholders; proxy solicitation.* As opposed to the Listing Rules of the NASDAQ Stock Market, which require listed issuers to make such reports available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. In addition to making such reports available on a public website, we currently make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- Ÿ *Nomination of our directors.* With the exception of our external directors and directors elected by our Board of Directors due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following one year from his or her election. See "Management—Board Practices—Board of Directors." The nominations for directors, which are presented to our shareholders by our Board of Directors, are generally made by the Board of Directors itself, in accordance with the provisions of our amended and restated articles of association and the Israeli Companies Law. Nominations need not be made by a nominating committee of our Board of Directors consisting solely of independent directors, or by a majority of independent directors, as required under the Listing Rules of the NASDAQ Stock Market.

- Ÿ *Compensation of officers.* Israeli law and our amended and restated articles of association do not require that the independent members of our Board of Directors (or a compensation committee composed solely of independent members of our Board of Directors) determine an executive officer's compensation, as is generally required under the Listing Rules of the NASDAQ Stock Market with respect to the Chief Executive Officer and all other executive officers.

Instead, compensation of executive officers is determined and approved by our Compensation Committee and our Board of Directors, and in certain circumstances by our shareholders, either in consistency with our office holder compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations stated in the Israeli Companies Law.

Shareholder approval is generally required for executive officer compensation in the event (i) approval by our Board of Directors and our Compensation Committee is not consistent with our office holders compensation policy, or (ii) compensation required to be approved is that of our chief executive officer who is not a director or an executive officer who is also the controlling shareholder of our company (including an affiliate thereof). Such shareholder approval shall require a majority vote of the shares present and voting at a shareholders meeting, provided either (i) such majority includes a majority of the shares held by non-controlling shareholders who do not otherwise have a personal interest in the compensation arrangement that are voted at the meeting, excluding for such purpose any abstentions disinterested majority, or (ii) the total shares held by non-controlling and disinterested shareholders voted against the arrangement does not exceed two percent (2%) of the voting rights in our company.

Additionally, approval of the compensation of an executive officer, who is also a director, shall generally require a simple majority vote of the shares present and voting at a shareholders meeting, if consistent with our office holders compensation policy. Our Compensation Committee and Board of Directors may, in special circumstances, approve the compensation of an executive officer (other than a director, a chief executive officer or a controlling shareholder) or approve the compensation policy despite shareholders' objection, based on specified arguments and taking shareholders' objection into account. Our Compensation Committee may further exempt an engagement with a nominee for the position of chief executive officer, who meets the non-affiliation requirements set forth for an external director, from requiring shareholders' approval, if such engagement is consistent with our office holders compensation policy and our Compensation Committee determines based on specified arguments that presentation of such engagement to shareholders' approval is likely to prevent such engagement. To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years.

A director or executive officer may not be present when the board of directors of a company discusses or votes upon the terms of his or her compensation, unless the chairman of the board of directors determines that he or she should be present to present the transaction that is subject to approval.

- Ÿ *Independent directors.* Israeli law does not require that a majority of the directors serving on our Board of Directors be "independent," as defined under NASDAQ Listing Rule 5605(a)(2), and rather requires we have at least two external directors who meet the requirements of the Israeli Companies Law, as described above under "Management—Board Practices—External Directors." We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable NASDAQ and SEC criteria for independence (as we cannot exempt ourselves from compliance with that SEC independence requirement, despite our status as a foreign private issuer), and we must also ensure that a majority of the members of our Audit Committee are "unaffiliated directors" as defined in the Israeli Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the NASDAQ Listing Rules otherwise require.

- Ÿ *Shareholder approval.* We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Israeli Companies Law, rather than seeking approval for corporation actions in accordance with NASDAQ Listing Rule 5635. In particular, under this NASDAQ rule, shareholder approval is generally required for: (i) an acquisition of shares/assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption/amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (and/or via sales by directors/officers/5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Israeli Companies Law, shareholder approval is required for, among other things: (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (ii) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described below under "Approval of Related Party Transactions under Israeli Law — Disclosure of personal interests of controlling shareholders", and (iii) terms of employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative, which require the special approval described below under "Approval of Related Party Transactions under Israeli Law — Disclosure of personal interests of controlling shareholders". In addition, under the Israeli Companies Law, a merger requires approval of the shareholders of each of the merging companies.

Approval of Related Party Transactions under Israeli Law

Disclosure of personal interests of a controlling shareholder and approval of transactions

The Companies Law also requires that a controlling shareholder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. A controlling shareholder’s disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder’s relative (including through a corporation controlled by a controlling shareholder), regarding the company’s receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of the engagement of the company, (ii) the board of directors and (iii) the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- Ÿ a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

- Ÿ the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2.0% of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years, however, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote.

ITEM 16H. Mine Safety Disclosure

Not applicable.

PART THREE

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The following consolidated financial statements, and the related notes thereto, and the Reports of Independent Public Accountants are filed as a part of this annual report.

ITEM 19. EXHIBITS

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1	Articles of Association of the Company, filed as Exhibit 3.2 to Form F-1/A filed on March 19, 2013 (File No. 333-186003) and incorporated herein by reference.
4.1	Form of Representative's Warrant Agreement, filed as Exhibit 4.2 to Form F-1/A filed on April 25, 2013 (File No. 333-186003) and incorporated herein by reference.
4.1	Consulting Agreement between the Company and Adler Consulting LLC, dated November 2010, filed as Exhibit 10.1 to Form F-1/A filed on January 14, 2013 (File No. 333-186003) and incorporated herein by reference.
4.2	Addendum to Services Agreement between the Company and Top-Notch Consulting 2009 Ltd., dated June 1, 2010, filed as Exhibit 10.2 to Form F-1/A filed on January 14, 2013 (File No. 333-186003) and incorporated herein by reference.
4.3	Alcobra Ltd. 2010 Incentive Option Plan, filed as Exhibit 10.3 to Form F-1/A filed on January 14, 2013 (File No. 333-186003) and incorporated herein by reference.
4.4	Form of Indemnification Agreement, filed as Exhibit 10.4 to Form F-1/A filed on February 19, 2013 (File No. 333-186003) and incorporated herein by reference.
4.5	Services Agreement between the Company and Ehud Gilboa, dated March 1, 2008, filed as Exhibit 10.5 to Form F-1/A filed on April 5, 2013 (File No. 333-186003) and incorporated herein by reference.
4.6	Addendum I to Services Agreement between the Company and Ehud Gilboa, dated March 14, 2013, filed as Exhibit 10.6 to Form F-1/A filed on April 5, 2013 (File No. 333-186003) and incorporated herein by reference.
4.7	Services Agreement between the Company and Dalia Megiddo, dated June 2, 2011, filed as Exhibit 10.7 to Form F-1/A filed on April 5, 2013 (File No. 333-186003) and incorporated herein by reference.
4.8	Addendum I to Services Agreement between the Company and Dalia Megiddo, dated March 14, 2013, filed as Exhibit 10.5 to Form F-1/A filed on April 5, 2013 (File No. 333-186003) and incorporated herein by reference.

4.9	Employment agreement between the Company and Yaron Daniely, dated March 4, 2010, filed as Exhibit 10.9 to Form F-1/A filed on April 25, 2013 (File No. 333-186003) and incorporated herein by reference.
4.10∞	Letter of Approval from the Office of Chief Scientist, filed as Exhibit 10.8 to Form F-1/A filed on February 19, 2013 (File No. 333-186003) and incorporated herein by reference
4.11	Employment agreement between the Company and Nir Peles, dated April 8, 2013, filed as Exhibit 10.11 to Form F-1/A filed on October 22, 2013 (File No. 333-191714) and incorporated herein by reference.
4.12	Employment agreement between the Company and Hanna Ron, dated June 1, 2013, filed as Exhibit 10.12 to Form F-1/A filed on October 22, 2013 (File No. 333-191714) and incorporated herein by reference.
4.13	Employment agreement between the Company and Jonathan Rubin, dated July 25, 2013, filed as Exhibit 10.13 to Form F-1/A filed on October 22, 2013 (File No. 333-191714) and incorporated herein by reference.
12.1	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
12.2	Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
13.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350
13.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350
101	The following materials from our Annual Report on Form 20-F for the year ended December 31, 2013 formatted in XBRL (eXtensible Business Reporting Language) are furnished herewith: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehensive Loss, (iii) the Consolidated Statements of Changes in Shareholders' Equity, (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

∞ English translation of original Hebrew document.

SIGNATURES

Alcobra Ltd. 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.

ALCOBRA LTD.

By: /s/ Dr. Yaron Daniely
Dr. Yaron Daniely
Chief Executive Officer and President

Date: March 28, 2014

ALCOBRA LTD. AND ITS SUBSIDIARY
(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2013

U.S. DOLLARS IN THOUSANDS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACOUNTING FIRM

To the Shareholders and Board of Directors of

ALCOBRA LTD. AND ITS SUBSIDIARY
(A development stage company)

We have audited the accompanying consolidated balance sheets of Alcobra Ltd. (a development stage company) ("the Company") and its subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of comprehensive loss, changes in shareholders' equity (deficiency) and cash flow for each of the three years in the period ended December 31, 2013 and for the period from February 7, 2008 (date of inception) to December 31, 2013. These financial statements are the responsibility of the Company's board of directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, based on our audits, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2013 and 2012, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 and for the period from February 7, 2008 (date of inception) to December 31, 2013, in conformity with generally accepted accounting principles in the United States.

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

Tel-Aviv, Israel
March 27th, 2014

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	December 31,	
	2013	**2012**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 22,095	$ 97
Short-term bank deposit	28,008	-
Receivables and prepaid expenses	115	83
Total current assets	50,218	180
LONG-TERM ASSETS:		
Other long-term assets	57	3
Property and equipment, net	49	18
Total long-term assets	106	21
TOTAL ASSETS	$ 50,324	$ 201

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

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2013	**2012**
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Trade payables	$ 47	$ 23
Accrued expenses and other liabilities	1,589	83
Convertible Notes	-	662
Total current liabilities	1,636	768
SHAREHOLDERS' EQUITY (DEFICIENCY):		
Ordinary shares of NIS 0.01 par value - 50,000,000 and 10,000,000 shares authorized at December 31, 2013 and 2012; 13,941,033 and 8,098,581 issued shares at December 31, 2013 and 2012, respectively; 13,636,709 and 7,794,256 shares outstanding at December 31, 2012, respectively	39	4
Treasury shares (304,324 ordinary shares at December 31, 2013 and 2012.)	*) -	*) -
Additional paid- in capital	67,383	7,615
Deficit accumulated during the development stage	(18,734)	(8,186)
Total shareholders' equity (deficiency)	48,688	(567)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)	$ 50,324	$ 201

*) Represents an amount less than $ 1.

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	December 31,			Period from February 7, 2008 (date of inception) to December 31,
	2013	2012	2011	2013
Research and development expenses, net	$ 7,066	$ 818	$ 1,822	$ 10,834
General and administrative expenses	3,224	683	2,084	7,266
Operating loss	10,290	1,501	3,906	18,100
Financial expenses, net	197	78	23	393
Tax expenses	61	-	-	61
Net comprehensive loss	$ 10,548	$ 1,579	$ 3,929	18,554
Deemed dividend	-	-	180	180
Net loss attributable to holders of ordinary shares	$ 10,548	$ 1,579	$ 4,109	$ 18,734
Net basic and diluted loss per share	$ (1.04)	$ (0.2)	$ (0.5)	
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	10,177,786	7,791,932	7,843,388	

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		Preferred A shares		Preferred B shares		Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficiency)
	Number	Amount	Number	Amount	Number	Amount			
Balance as of February 7, 2008 (date of inception)	-	$ -	-	$ -	-	$ -	$ -	$ -	$ -
Issuance of ordinary shares at par share	5,752,600	3	-	-	-	-	-	-	3
Issuance of Preferred A shares, net ($0.92 per share)	-	-	747,339	*) -	-	-	657	-	657
Preferred A shares issued to service provider ($0.92 per share)	-	-	81,528	*) -	-	-	75	-	75
Share based compensation related to warrants granted to consultant	-	-	-	-	-	-	28	-	28
Net loss	-	-	-	-	-	-	-	(666)	(666)
Balance as of December 31, 2008	5,752,600	$ 3	828,867	$ *) -	-	$ -	$ 760	$ (666)	$ 97
Issuance of Preferred A shares, net ($0.92 per share)	-	-	203,818	*) -	-	-	187	-	187
Issuance of Preferred A shares granted to service provider ($0.92 per share)	-	-	190,229	*) -	-	-	175	-	175
Conversion of Preferred A shares into ordinary shares	461,987	*) -	(461,987)	*) -	-	-	-	-	*) -
Net loss	-	-	-	-	-	-	-	(608)	(608)
Balance as of December 31, 2009	6,214,587	$ 3	760,927	$ *) -	-	$ -	$ 1,122	$ (1,274)	$ (149)
Issuance of Preferred B shares and warrants, net ($2.18 per unit of 1 share and 0.25 warrant)	-	-	-	-	342,691	*) -	723	-	723
Issuance of Preferred B shares and warrants upon conversion of convertible notes ($1.75 per unit of 1 share and 0.25 warrant)	-	-	-	-	128,512	*) -	279	-	279
Issuance of Preferred B shares and warrants granted to service provider	-	-	-	-	55,008	*) -	120	-	120
Share based compensation related to options granted to a service provider and employees	-	-	-	-	-	-	242	-	242
Exercise of options	288,681	*) -	-	-	-	-	*) -	-	*) -
Net loss	-	-	-	-	-	-	-	(1,224)	(1,224)
Balance as of December 31, 2010	6,503,268	$ 3	760,927	$ *) -	526,211	$ *) -	$ 2,486	$ (2,498)	$ (9)

*) Represents an amount less than $ 1.

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		Preferred A shares		Preferred B shares		Additional paid-in	Deficit accumulated during the development	Total shareholders' equity
	Number	Amount	Number	Amount	Number	Amount	capital	stage	(deficiency)
Balance as of December 31, 2010	6,503,268	$ 3	760,927	$ *) -	526,211	$ *) -	$ 2,486	$ (2,498)	$ (9)
Conversion of Preferred A and B shares into ordinary shares	1,287,138	1	(760,927)	*) -	(526,211)	*) -	(1)	-	-
Deemed dividend in respect of equity restructuring	-	-	-	-	-	-	180	(180)	-
Issuance of ordinary shares upon conversion of loan into ordinary shares net ($11.5 per share)	104,345	*) -	-	-	-	-	1,200	-	1,200
Issuance of ordinary shares, net ($11.5 per share)	199,979	*) -	-	-	-	-	2,170	-	2,170
Exercise of options	1,379	*) -	-	-	-	-	*) -	-	*) -
Share based compensation related to options granted to consultants and employees	-	-	-	-	-	-	1,553	-	1,553
Net loss	-	-	-	-	-	-	-	(3,929)	(3,929)
Balance as of December 31, 2011	8,096,109	$ 4	-	$ *) -	-	$ *) -	$ 7,588	$ (6,607)	$ 985
Treasury shares	(304,324)	*) -	-	-	-	-	-	-	*) -
Exercise of options	2,471	*) -	-	-	-	-	1	-	1
Share based compensation related to options granted to consultants and employees	-	-	-	-	-	-	26	-	26
Net loss	-	-	-	-	-	-	-	(1,579)	(1,579)
Balance as of December 31, 2012	7,794,256	$ 4	-	$ *) -	-	$ *) -	$ 7,615	$ (8,186)	$ (567)
Exercise of options	208,708	1	-	-	-	-	28	-	29
Issuance of shares upon cashless exercise of warrants	85,192	*) -	-	-	-	-	-	-	*) -
Issuance of shares upon conversion of convertible notes	123,553	*) -	-	-	-	-	980	-	980
Issuance of shares upon initial public offering ($8 per share), net of $3,080 issuance expenses	3,125,000	28	-	-	-	-	21,892	-	21,920
Issuance of shares upon secondary public offering ($16.5 per share), net of $2,616 issuance expenses	2,300,000	6	-	-	-	-	35,328	-	35,334
Share based compensation related to options granted to consultants and employees	-	-	-	-	-	-	1,540	-	1,540
Net loss	-	-	-	-	-	-	-	(10,548)	(10,548)
Balance as of December 31, 2013	13,636,709	$ 39	-	$ *) -	-	$ *) -	$ 67,383	$ (18,734)	$ 48,688

*) Represents an amount less than $ 1.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,			Period from February 7, 2008 (date of inception) to December 31,
	2013	2012	2011	2013
Cash flows from operating activities				
Net loss	$ (10,548)	$ (1,579)	$ (3,929)	$ (18,554)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	8	7	6	30
Stock based compensation	1,540	26	1,553	3,759
Gain from sale of property and equipment	1	-	-	1
Decrease (increase) in receivables and prepaid expenses	(32)	12	(49)	(115)
Decrease (increase) in other long-term assets	(54)	2	-	(57)
Increase (decrease) in trade payables	24	(101)	95	47
Increase (decrease) in accrued expenses and other liabilities	1,505	(12)	(37)	1,588
Interest on convertible notes	203	62	-	324
Net cash used in operating activities	(7,353)	(1,583)	(2,361)	(12,977)
Cash flows from investing activities				
Purchase of property and equipment	(39)	-	(24)	(79)
Proceeds from (investment in) short-term bank deposit	(28,008)	517	(517)	(28,008)
Proceeds from (investment in) restricted bank deposit	-	507	(500)	-
Net cash provided by (used in) investing activities	(28,047)	1,024	(1,041)	(28,087)
Cash flows from financing activities				
Proceeds from issuance of convertible notes	115	600	-	935
Issuance of share capital upon public offering	57,254	-	-	57,254
Exercise of options	29	-	-	29
Proceeds from loan	-	-	450	1,200
Issuance of shares, net	-	1	2,170	3,741
Net cash provided by financing activities	57,398	601	2,620	63,159
Increase (decrease) in cash and cash equivalents	21,998	42	(782)	22,095
Cash and cash equivalents at the beginning of the period	97	55	837	-
Cash and cash equivalents at the end of the period	$ 22,095	$ 97	$ 55	$ 22,095
Supplemental disclosure of non-cash investing and financing activities:				
Issuance of ordinary shares upon conversion of convertible notes	$ 980	$ -	$ -	$ 980
Issuance of ordinary shares upon conversion of loans	$ -	$ -	$ 1,200	$ 1,200

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

NOTE 1:- GENERAL

a. Alcobra Ltd. was incorporated in Israel and commenced its operation on February 7, 2008. During July 2013, a wholly- owned subsidiary was established in the state of Delaware named Alcobra Inc. (the "Subsidiary"). Alcobra Ltd. and its Subsidiary (collectively "the Company") are an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug candidate, to treat Attention Deficit Hyperactivity Disorder, ("ADHD"), and other potential cognitive dysfunctions including Fragile X. The Company's objective is to conduct additional clinical trials for its drug called MDX (the "Drug") and, if those trials are successful, seek marketing approval from the U.S. Food and Drug Administration (the "FDA") and other worldwide regulatory bodies.

b. The Company has not generated revenue from the sale of any product, and does not expect to generate significant revenue unless and until obtaining of marketing approval and commercializing the MDX. Accordingly, the Company is considered to be in the development stage as defined in ASC 915, "Development stage entities". The Company has incurred losses in the amount of $ 10,548 thousand during the year ended December 31, 2013. The Company has an accumulated deficit in the total amount of $ 18,734 as of December 31, 2013 and as of that date the accumulated negative cash flow from operating activity is in the amount of $ 12,977.

The Company believes that its existing cash and cash equivalents and short term bank deposits should be sufficient to meet its operating and capital requirements through 2016.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

a. Use of estimates:

The preparation of the 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

b. Financial statements in U.S. dollars:

The Company finances its operations in U.S. dollars. The majority of the Company's operations are currently conducted in Israel, a significant part of the Company's expenses are denominated and determined in U.S. dollars. The Company's management believes that the dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. Thus, the functional and reporting currency of the Company is the U.S. dollar.

The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-dollar transactions and balances have been remeasured to U.S. dollars in accordance with ASC 830, "Foreign Currency Matters", of the Financial Accounting Standards Board ("FASB"). All transaction gains and losses from remeasurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of operations as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of Alcobra Ltd. and its Subsidiary. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash equivalents:

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

e. Short-term bank deposit

Short-term bank deposits are deposits with maturities of more than three months but less than one year. The short–term bank deposits are presented at their cost, including accrued interest, which approximates fair value. As of December 31, 2013, the Company's bank deposits were in U.S. dollars and bore interest at a weighted average interest rate of 0.42%.

U.S. dollars in thousands, except share data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

f. Property and equipment, net:

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

	%
Computers and electronic equipment	15-33
Office furniture and equipment	6
Clinical and medical equipment	15-33
Leasehold improvement	The shorter of term of the lease or the useful life of the asset

The Company's property and equipment 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 an asset 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. In 2013 and 2012, no impairment losses have been identified.

g. Long-term deposits:

Long-term deposits include long-term deposits for office lease prepaid deposit and motor vehicles under operating leases, presented at their cost.

h. Research and development expenses:

Research and development expenses are expensed as incurred. Those expenses include payments to third party clinical consultants, expenses related to conducting clinical and pre-clinical trials, salaries and related personnel expenses, travel expenses, and share based compensation expenses to research and development employees. During 2013, 2012 and 2011, no grants were received.

i. Severance pay:

The Company's liability for its Israeli employees regarding severance pay is pursuant to Section 14 of the Israeli severance pay law ("Section 14"). All the Israeli employees are included under this section, and entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made in the employee's name with insurance companies. Payments in accordance with Section 14 release the Company from any future severance payments in respect of those employees. The fund is made available to the employee at the time the employer-employee relationship is terminated, regardless of cause of termination. The severance pay liabilities and deposits under Section 14 are not reflected in the balance sheet as the severance pay risks have been irrevocably transferred to the severance funds.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Severance pay expense for the years ended December 31, 2013, 2012 and 2011, amounted to $ 26, $ 18 and $ 14, respectively.

j. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). 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, to reduce deferred tax assets to the amount that is more likely than not to be realized.

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

The Company believes that its tax positions are all highly certain of being upheld upon examination. As such, as of December 31, 2013 and 2012 the Company has not recorded a liability for uncertain tax positions.

k. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, and short term bank deposit.

Cash and cash equivalents and short term bank deposit are invested in major banks in Israel and the deposits in the U.S. may be in excess of insured limits and are not insured in other jurisdictions. Generally, these deposits may be redeemed upon demand and therefore bear minimal risk.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

l. Fair value of financial instruments:

The Company has no financial instruments that are measured at fair value.

The carrying amounts of cash and cash equivalents, short term bank deposits, accounts receivable and accounts payable, approximate their fair value due to the short-term maturities of such instruments.

m. 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."

The total weighted average number of shares related to the outstanding options and warrants excluded from the calculations of diluted net loss per share, since they would have an anti-dilutive effect, was 873,031, 537,690 and 561,198 for the years ended December 31, 2013, 2012 and 2011, respectively.

n. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation" ("ASC 718") that requires the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to employees and directors. 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 option award is recognized as an expense over the requisite service periods in the Company's statements of operations based on the accelerated method.

The Company selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the fair value method for of its stock-options awards. The option-pricing model requires a number of assumptions as noted below:

Expected dividend yield - The expected 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.

Volatility - Since the Company's shares started trading in NASDAQ in May 2013, sufficient quoted prices of the Company's share are unavailable. Due to insufficient historical data for the Company, the expected volatility determination was based on similar companies' stock volatility.

Risk free interest rate - The risk free interest rate is based on the yield of U.S Treasury bonds with equivalent terms.

U.S. dollars in thousands, except share data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Expected term - ASC 718 provides the factors to consider when estimating the expected term of an option: An option's expected term must at least include the vesting period and the employees' historical exercise and post-vesting employment termination behavior for similar grants. It also determines that if the amount of past exercise data is limited, that data may not represent a sufficiently large sample on which to base a robust conclusion on expected exercise behavior. In that circumstance, it may be appropriate to consider external data or the SEC staff's "simplified" method for the expected term. Accordingly, The Company used the "simplified" method, meaning the expected life can be set as the average of the vesting period for each vested tranche of options and the contractual term for those options.

NOTE 3:- RECEIVABLES AND PREPAID EXPENSES

	December 31,	
	2013	**2012**
Government authorities	$ 46	$ 10
Prepaid expenses	18	66
Other current assets	51	7
	$ 115	$ 83

NOTE 4: PROPERTY AND EQUIPMENT, NET

	December 31,	
	2013	**2012**
Cost:		
Computers and electronic equipment	$ 32	$ 19
Office furniture and equipment	23	7
Leasehold improvement	5	-
Clinical and medical equipment	19	14
	79	40
Accumulated depreciation:		
Computers and electronic equipment	17	13
Office furniture and equipment	2	1
Leasehold improvement	1	-
Clinical and medical equipment	10	8
	30	22
Depreciated cost	$ 49	$ 18

Depreciation expenses for the years ended December 31, 2013, 2012 and 2011, were $ 8, $ 7 and $ 6, respectively.

U.S. dollars in thousands, except share data

NOTE 5:- ACCRUED EXPENSES AND OTHER LIABILITIES

	December 31,	
	2013	2012
Employees and payroll accruals	$ 264	$ 31
Accrued expenses	1,264	52
Government authorities	61	-
	$ 1,589	$ 83

NOTE 6:- CONVERTIBLE NOTES

During 2012 and 2013, the Company issued convertible promissory notes to certain investors for a total amount of $ 715. The convertible notes bore an annual interest rate of 6%.

In connection with the Company's Initial Public Offering, ("IPO"), in May 2013, according to the terms of the convertible notes, in May 2013 the notes were automatically converted into 123,553 ordinary shares of the Company. Upon conversion of the convertible notes, the entire redemption amount was derecognized against additional paid in capital in the amount of $ 980. The financial expenses for the years ended December 31, 2013 and 2012, amounted to $ 203 and $ 52, respectively.

NOTE 7:- INCOME TAXES

a. Tax laws applicable to Alcobra Ltd. and the Subsidiary:

1. Alcobra Ltd. is taxed under the Israeli income tax law.

2. The Subsidiary is taxed under U.S. tax law.

b. Tax rates applicable to the Company and the Subsidiary:

1. Alcobra Ltd:

Taxable income of Israeli companies is subject to tax at the rate of 25% in 2012 and in 2013 and a rate of 26.5% commencing January 1, 2014.

2. The Subsidiary:

The federal tax rates applicable to the Company whose place of incorporation is within the U.S. are corporate (progressive) tax at the rate of up to 35%, excluding state tax, which rates depend on the state in which the Company conducts its business.

U.S. dollars in thousands, except share data

NOTE 7:- INCOME TAXES (Cont.)

c. Net operating losses carry forward:

Alcobra Ltd. has accumulated losses for tax purposes in Israel as of December 31, 2013 in the amount of approximately $ 10,241 which may be carried forward and offset against taxable income in the future for an indefinite period.

d. Deferred income 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. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2013	**2012**
Operating loss carry forward	$ 2,713	$ 1,153
Reserves and allowances	1,358	308
Deferred tax assets before valuation allowance	4,071	1,461
Valuation allowance	(4,071)	(1,461)
Net deferred tax assets	$ -	$ -

All deferred taxes are domestic. Management currently believes that since the Company has a history of losses it is more likely than not that the deferred tax regarding the loss carry forward and other temporary differences will not be realized in the foreseeable future.

e. No liability for uncertain tax positions was recorded as a result of implementation of ASC 740.

f. 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 due to the uncertainty of the realization of such deferred taxes.

g. Net comprehensive loss (income) before taxes on income is comprised as follows:

	December 31,		
	2013	**2012**	**2011**
Domestic (Israel)	$ 10,505	$ 1,579	$ 3,929
Foreign (U.S)	(18)	-	-
	$ 10,487	$ 1,579	$ 3,929

h. Taxes on income relate solely to the foreign Subsidiary.

U.S. dollars in thousands, except share data

NOTE 8:- CONTINGENT LIABILITIES AND COMMITMENTS

a. The Company is engaged in two operating lease agreements for its facilities. The rent expenses for the years ended December 31, 2013, 2012 and 2011, amounted to $ 50, $ 44 and $ 61, respectively. Future minimum payments under the leases are as follows:

Year ended December 31,	Total
2014	$ 122
2015	102
2016	73
	$ 297

b. On June 2013 the Company entered into a new operating lease agreement for its vehicles until 2016. The rent expenses for the year ended December 31, 2013, 2012 and 2011, amounted to $ 51, $ 18 and $ 29, respectively. Future minimum payments under the lease are as follows:

Year ended December 31,	Total
2014	$ 48
2015	41
2016	22
	$ 111

c. Royalty bearing Government grants:

The Company partially financed its research and development expenditures under programs sponsored by the Office of Chief Scientist ("OCS") for the support of certain research and development activities conducted in Israel.

In connection with its research and development, the Company received $ 106 of participation payments from the OCS through December 31, 2013. In return for the OCS's participation, the Company is committed to pay royalties at a rate of 3%-5% of sales of the developed product linked to U.S dollars, up to 100% of the amount of grants received (100% plus interest at LIBOR). The Company's total commitment for royalties payable with respect to future sales, based on OCS participations received or accrued, net of royalties paid or accrued, totaled approximately $ 115 as of December 31, 2013. In addition, the OCS may impose certain conditions on any arrangement under which it permits the Company to transfer technology or development out of Israel.

NOTE 9:- SHAREHOLDERS' EQUITY (DEFICIENCY)

a. General:

1. All ordinary shares, options, warrants, per share data, exercise price and convertible notes conversion ratio included in these financial statements for all periods presented have been retroactively adjusted to reflect the issuance on May 19, 2013 of 4.87-to-one bonus shares (equivalent to a 5.87-for-1 stock split).

2. During March 2013, the Company's general meeting resolved to increase the Company's authorized shares from 10,000,000 to 50,000,000 ordinary shares.

b. Share capital:

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.

c. Issuances of share:

1. During May 2013, the Company completed an IPO and listed its ordinary shares on the "NASDAQ Capital Market" and issued 3,125,000 ordinary shares in consideration of approximately $21,920, net.

   Following the IPO and according to the terms of the convertible notes, the notes were automatically converted into 123,553 ordinary shares of the Company. In addition, 120,255 warrants were exercised into 85,192 ordinary shares of the Company, using the cashless exercise method.

2. During October 2013, the Company completed a secondary public offering in the "NASDAQ Capital Market" and issued 2,300,000 ordinary shares in consideration of approximately $35,334, net.

d. 2010 incentive option plan:

In February 2010, the Company authorized through its 2010 incentive option plan (the "2010 Plan") the grant of options to officers, directors, advisors, management and other key employees. The Company reserved for grants of options up to 1,693,047 of the Company's ordinary shares. The options granted have generally four year vesting terms and expire ten years after the grant date. As of December 31, 2013, 372,725 options were still available for future grants under the Plan.

U.S. dollars in thousands, except share data

NOTE 9:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

A summary of the Company's options activity (for employees and directors) under the 2010 Plan is as follows:

	Year ended December 31,			
	2013		2012	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	461,118	$ 0.20	465,520	$ 0.21
Granted *)	552,890	$ 9.87	-	-
Exercised	(208,708)	$ 0.14	(2,471)	$ 0.33
Forfeited	-		(1,931)	$ 0.33
Outstanding at end of year	805,300	$ 6.86	461,118	$ 0.2
Vested and expected to vest	805,300	$ 6.86	461,118	$ 0.2
Options exercisable at the end of the period	308,909	$ 0.33	366,464	$ 0.22

As of December 31, 2013, the weighted-average remaining contractual term of the outstanding and exercisable options is 8.19 and 6.37 years; the aggregated intrinsic value of outstanding and exercisable options is $ 8,957 and $ 5,459, respectively. As of December 31, 2013, the unrecognized compensation cost is $ 1,921 and $ 603 to be recognized in 2014 and 2015, respectively.

*) Including 22,388 and 102,275 options to purchase ordinary shares granted in May and December 2013 to a director and an employee, respectively. The exercise price is $ 8 and $ 17.6, respectively. The vesting of the options is subject to certain performance conditions. As of December 31, 2013, the performance conditions are probable and the Company recorded share based expenses in the amount of $ 109.

e. Options granted to consultants:

The Company granted options to certain service providers and accounted for these options in accordance with ASC 505-50, "Equity-Based payment to non-employees".

The outstanding options granted to the Company's consultants are as follows:

Grant date	Number of options	Exercise price	Expiration date
April 2, 2008	58,700	0.0005	April 2, 2018
February 28, 2010	8,805	2.1840	February 28, 2020
February 13, 2011	1,174	0.0005	February 13, 2021
February 17, 2011	3,804	0.0005	February 17, 2021
	72,483*)		

*) All options were fully vested on grant date.

U.S. dollars in thousands, except share data

NOTE 9:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

f. Warrants granted to underwriters:

The outstanding options granted to the underwriters for the IPO are as follows:

Grant date	Number of options	Exercise price	Expiration date
May 28, 2013	52,083	12	May 28, 2015
May 28, 2013	52,083	16	November 28, 2015
May 28, 2013	52,084	20	May 28, 2016
	156,250		

g. Share-based payment:

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,			Period from February 7, 2008 (date of inception) to December 31,
	2013	2012	2011	2013
Research and development, net	$ 430	$ *) -	$ 18	$ 913
General and administrative expenses	1,110	26	1,535	2,846
	$ 1,540	$ 26	$ 1,553	$ 3,759

*) Represents an amount less than $ 1.

NOTE 10:- RELATED PARTY BALANCES AND TRANSACTIONS

Balances with related parties:

	December 31,	
	2013	2012
Convertible notes (e)	$ -	$ 610
Other accounts payable (c) (d)	$ 47	$ 21

U.S. dollars in thousands, except share data

NOTE 10:- RELATED PARTY BALANCES AND TRANSACTIONS (Cont.)

Related parties' expenses:

	Year ended December 31,		
	2013	**2012**	**2011**
Amounts charged to: *)			
Research and development expenses (b) (d)	$ 341	$ -	$ -
General and administrative expense (a) (b) (c) (d)	$ 1,266	$ 401	$ 1,786
Financial expense (e)	$ -	$ 60	$ -

*) Including share based compensation expenses for the years ended December 31, 2013, 2012 and 2011, in the amounts of $ 841, $ 26 and $ 1,394, respectively.

a. On March 1, 2008, the Company signed an agreement with a consultant, who is also one of the Company's shareholders and a director, as a contractor to render management, finance and operation services. The Company pays the consultant an amount of $ 7 per month. During May 2013, the monthly fee was increased to an amount of $ 12. The amendment was effective upon consummation of the IPO in May 2013. In June 2013, and in connection to the consummation of the IPO, the Company granted the consultant a bonus in the amount of $50. (see also Note 12 (a)).

b. The Company signed an agreement with a company owned by one of its related parties. Under the agreement, the company renders the Company with office services and office lease for a monthly fee in the amount of approximately $ 4 since June 1, 2010. Each party may terminate the agreement with 30-days' notice. The agreement was terminated in September 2013.

c. An agreement was signed on June 2, 2011 between the Company and one its shareholders, as a contractor to render services related to pre-clinical, clinical, regulatory and intellectual property issues, for an amount of approximately $ 3 per month. During May 2013, the monthly fee was increased to an amount of $ 5. The amendment was effective upon consummation of the IPO in May 2013.

U.S. dollars in thousands, except share data

NOTE 10:- RELATED PARTY BALANCES AND TRANSACTIONS (Cont.)

d. Under the employment agreement, dated March 4, 2010, with the Company's Chief Executive Officer and Director, and following a salary increase approved April 14, 2011, the CEO was entitled to a gross monthly salary of $ 14. During January 2013, the Company increased the monthly salary to an amount of $ 15 which became effective upon the Company's IPO. In June 2013, the Company granted the CEO a bonus in the amount of $ 75 in connection with the consummation of the IPO and in August 2013, the Company increased the bonus amount in $ 125, to a total of $ 200. (see also Note 12 (a)).

e. One of the Company's shareholders invested as part of the Company's issuance of the Convertible notes.

NOTE 11:- FINANCIAL EXPENSES, NET

	Year ended December 31,			Period from February 7, 2008 (date of inception) to December 31,
	2013	2012	2011	2013
Financial expenses:				
Interest expense	$ -	$ 3	$ 3	$ 23
Exchange rate	7	15	41	99
Bank fees	9	-	-	9
Interest on convertible notes	203	62	-	310
	219	80	44	441
Financial income:				
Interest income	22	2	21	48
	22	2	21	48
	$ 197	$ 78	$ 23	$ 393

NOTE 12:- SUBSEQUENT EVENTS

a. During February 2014, the Company's shareholders resolved to grant the Company's CFO and CEO bonuses in the amount of $ 200 and $ 200, respectively. (see also Note 10 (a) and (d)). In addition, the shareholders had approved a grant of 150,000 options to the CEO.

b. During February and March 2014, the Company's Board of Directors resolved to grant an aggregate number of 155,000 options to two employees.

c. During March 2014, the Company's board of directors resolved to increase the number of options available for future grant under the option plan by 172,725.

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Exhibit 12.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Dr. Yaron Daniely, certify that:

1. I have reviewed this annual report on Form 20–F of Alcobra Ltd.;

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

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

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 28, 2014

/s/Dr. Yaron Daniely
Dr. Yaron Daniely
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Ehud (Udi) Gilboa, certify that:

1. I have reviewed this annual report on Form 20–F of Alcobra Ltd.;

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

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

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 28, 2014

/s/ Ehud (Udi) Gilboa
Ehud (Udi) Gilboa
Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2013 (the “Report”) by Alcobra Ltd. (the "Company"), the undersigned, as Chief Executive Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Dr. Yaron Daniely
Dr. Yaron Daniely
Chief Executive Officer
March 28, 2014

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2013 (the “Report”) by Alcobra Ltd. (the "Company"), the undersigned, as Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Ehud (Udi) Gilboa
Ehud (Udi) Gilboa
Chief Financial Officer
March 28, 2014