

2,000,000 Ordinary Shares

This is a public offering of our ordinary shares.

Our ordinary shares are listed on the NASDAQ Capital Market under the symbol "ADHD." The last reported sale price of our ordinary shares on October 24, 2013 was \$17.10 per share. We are offering all of the ordinary shares offered by this prospectus.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and will be subject to reduced public company reporting requirements.

Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 7.

	Per	Per Share		Total		
Public offering price	\$	16.50	\$	33,000,000		
Underwriting discounts and commissions <sup>(1)</sup>	\$	0.99	\$	1,980,000		
Proceeds to us (before expenses)	\$	15.51	\$	31,020,000		

(1) In addition to underwriting discounts and commissions payable by us, we have agreed to reimburse the underwriters for certain expenses. See "Underwriting".

We have granted a 30-day option to the underwriters to purchase up to 300,000 additional ordinary shares solely to cover over-allotments, if any ...

The underwriters expect to deliver the shares to purchasers in the offering on or about October 30, 2013.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Joint Book Running Managers

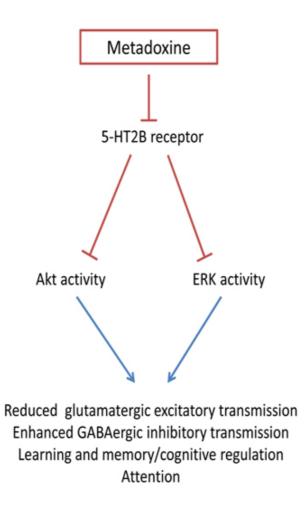
Stifel

**Aegis Capital Corp** 

Co-Lead Manager JMP Securities

The date of this prospectus is October 24, 2013.

### Metadoxine-mediated intracellular pathways



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You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. We are offering to sell our ordinary shares, and seeking offers to buy our ordinary shares, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our ordinary shares.

Until and including November 18, 2013, 25 days after the date of this prospectus, all dealers that buy, sell or trade our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

In this prospectus, "we," "us," "our," the "Company" and "Alcobra" refer to Alcobra Ltd. and its wholly owned subsidiary, Alcobra, Inc.

Our reporting currency and functional currency is the U.S. dollar.

### **PROSPECTUS SUMMARY**

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our ordinary shares. Before you decide to invest in our ordinary shares, you should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes appearing at the end of this prospectus.

#### **Our Company**

We are an emerging biopharmaceutical company primarily focused on the development and commercialization of our proprietary drug candidate, MG01CI, to treat both adult and pediatric Attention Deficit Hyperactivity Disorder, or ADHD, and other potential cognitive dysfunctions, including Fragile X Syndrome, or 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. MG01CI is a non-stimulant with a different mechanism of action. MG01CI 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 Israel in adult ADHD subjects 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.

We have initiated discussions with the U.S. Food and Drug Administration, or FDA, to seek approval, via an Investigational New Drug, or IND, Application submission, to conduct advanced clinical trials in the United States for the use of MGO1CI to treat ADHD in adults. If such FDA approval of our IND Application is granted and if these and any future clinical trials demonstrate the safety and efficacy of MGO1CI, we will seek to obtain marketing approval from the FDA for MG01CI 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. 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 5% and 12% 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 46% of all adults who had ADHD as children continuing to have symptoms of the disorder as adults. Approximately 95% of these adults experience impaired inattention 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. 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 prescribed with stimulants renew their prescription the following month. There also is a non-stimulant drug on the market called Strattera (Atomoxetine), approved in 2002. This drug also has significant side effects, such as fatigue, decreased appetite, 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 (Intuniv (Guanfacine) and Kapvay (Clonidine)). These two drugs are not approved for adults 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, MG01CI is a non-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. The trial also demonstrated favorable tolerability with no significant side effects over a placebo. MG01CI 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 executive function, we believe that MG01CI possibly may be useful in treating additional cognitive disorders. Accordingly, recently we have completed a pre-clinical study evaluating MG01CI in the standard mouse model of Fragile X (FMR1 knockout mouse). The study showed significant improvement in cognitive and social functioning following treatment with MG01CI in the Fragile X model.

Fragile X, an unmet medical need and a rare disease, as such term is 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 the U.S. 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 (macro-orchidism) 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.

The Fragile X study we completed included multiple behavioral assessments of 40 mice, comprising 20 Fragile X knock-out mice and 20 control littermate mice that were treated with MG01CI or a 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, and Y-maze alternation (a test of learning and perseverance). The individuals who rated these tests 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 MG01CI 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 and other cognitive disorders.

#### **Our Strategy**

Our objective is to develop and commercialize proprietary pharmaceutical products for the treatment of central nervous system disorders and cognitive dysfunctions in particular. To this effect, we intend to conduct additional clinical trials for MG01CI and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies for MG01CI for the treatment of ADHD in adults, children and adolescents. We also plan to advance clinical studies and commercialization plans for MG01CI in additional indications of cognitive dysfunction which present significant market opportunities such as Fragile X (a rare disease, as such term is defined by the Orphan Drug Act) and Shift Work Sleep Disorder, a cognitive disorder associated with an abnormal sleep pattern.

To achieve these objectives, we plan to:

- Ÿ subject to receiving the necessary regulatory approvals, initiate and complete two Phase 3 clinical trials of MG01CI for the treatment of ADHD in adults, and, if they are successful, file for marketing approval for adults initially in the U.S. and the EU;
- Ÿ subject to receiving the necessary regulatory approvals, initiate and complete clinical trials in a pediatric ADHD population, and, if successful, file for marketing approval for that use in the U.S. and EU;
- Ÿ pending securing additional funding and subject to receiving the necessary regulatory approvals, initiate and complete clinical trials in Japan for both adult and pediatric ADHD, and, if successful, file for marketing approval of such uses in that country;
- Ϋ́ if we receive marketing approval, prepare to commercialize MG01CI for the treatment of patients with ADHD by establishing distribution capabilities primarily in conjunction with large pharmaceutical companies;
- Ÿ conduct clinical investigations into the possible use of MG01CI to treat other cognitive disorders and impairments such as Fragile X and Shift Work Sleep Disorder;

#### **Corporate Information**

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 prospectus. We have included our website address in this prospectus 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 Jumpstart Our Business Startups Act of 2012, or 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.

#### **Risks Associated with Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our ordinary shares. In particular, our risks include, but are not limited to, the following:

- We depend entirely on the success of our only current product candidate, MG01CI, for the treatment of ADHD and other cognitive disorders. We have not received FDA approval to conduct the clinical trials that are necessary to receive regulatory approval to market MG01CI. We require additional and more complex clinical trials of MG01CI that must be successful if we are to seek and obtain regulatory marketing clearances. Advanced clinical trials are often not successful even if prior trials were successful, and even if we are able to conduct advanced clinical trials and those trials are successful, we may not obtain necessary regulatory approvals for MG01CI or we may be unable to successfully commercialize it even if we receive the necessary regulatory approvals.
- Ÿ Our data from future clinical trials may not satisfy the FDA, or the FDA may require additional time or studies to assess the safety and efficacy of MG01CI.



- Ÿ 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, MG01CI. We are unable to predict the extent of future losses or when we will become profitable based on the sale of any product, if at all. Even if we succeed in developing and commercializing our product candidate, we may never generate sufficient revenue to sustain profitability. As of June 30, 2013, we had an accumulated deficit of \$9.9 million.
- We have no sources of revenue and may need to raise substantial additional capital to successfully commercialize MG01CI, and such capital may not be available to us or available only on unfavorable terms.
- Ÿ We have one issued patent in the United States relating to our MG01CI technology and have filed patent applications with the U.S. Patent and Trademark Office, or U.S. PTO, and in other jurisdictions around the world. Our patent applications may not result in issued patents, and, even if issued, those patents may be challenged by our competitors. Any such challenge would be extremely expensive and distracting, and if we cannot successfully defend our intellectual property, competitors may be able to develop generic versions of MG01CI, which would have a material adverse effect on our business or even force us to cease operations.
- Ϋ́ As a public company, we need to comply with extensive additional governmental regulations, which will be expensive and which will require significant management attention.

#### THE OFFERING

Ordinary shares offered by us	2,000,000 shares
Ordinary shares to be outstanding after this offering	13,128,001 shares
Over-allotment option	The underwriters have an option for a period of 30 days to purchase up to 300,000 additional ordinary shares to cover over-allotments, if any.
Use of proceeds	We estimate that the net proceeds from our issuance and sale of 2,000,000 ordinary shares in this offering will be approximately \$30.7 million, based on the offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and offering expenses payable by us. If the representative of the underwriters exercises the over-allotment option in full, we estimate that the net proceeds from this offering will be approximately \$35.4 million, based on the offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and offering expenses payable by us. We currently expect to use the net proceeds from this offering for:
	• completing the required advanced clinical trials, that, if successful, would allow us to request drug approval of MG01CI to treat children and adults with Fragile X, estimated at \$14,000,000;
	<ul> <li>completing necessary preparations and conducting a Phase 3 clinical trial in pediatric ADHD for MG01CI, estimated at \$10,000,000; and</li> </ul>
	• the remainder for working capital and general corporate purposes.
Risk factors	You should read the "Risk Factors" section starting on page 7 of this prospectus for a discussion of factors to consider carefully before deciding to invest in ordinary shares.
NASDAQ Capital Market Symbol	"ADHD"

The number of our ordinary shares to be outstanding immediately after this offering is based on 11,128,001 ordinary shares outstanding as of October 1, 2013. This number excludes:

- Ÿ 900,516 shares issuable upon the exercise of share options outstanding as of October 1, 2013 under our equity incentive plan;
- Ÿ an undertaking to issue options to purchase up to 0.75% of the issued and outstanding shares of the Company issuable to an employee of the Company upon meeting certain milestones (such options, if and when issued, to be subject to a three year vesting schedule); and
- Ÿ 214,950 shares issuable upon the exercise of warrants outstanding as of October 1, 2013.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the underwriters' over-allotment option.

### SUMMARY FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statements of operations data for the periods of six months ended June 30, 2013 and 2012 and balance sheet data as of June 30, 2013 from our unaudited financial statements included elsewhere in this prospectus and the statements of operations data for the years ended December 31, 2012 and 2011 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

### (in thousands of U.S. dollars, except

share and per share amounts)

		Six Months Ended June 30,		Year Ended		Year Ended		
		2013 (unaudited)		2012 (unaudited)	D	ecember 31, 2012	De	cember 31, 2011
Statements of Operations Data:		(unuuuncu)		(unuuuncei)				
Research and development expenses	\$	396	\$	632	\$	818	\$	1,822
	Ψ	550	Ψ	002	Ψ	010	Ψ	1,022
General and administrative expenses		1,114		356		683		2,084
Financial expense, net		206		13		78		23
Deemed dividend		-		-		-		180
Loss attributable to holders of ordinary shares	\$	1,716	\$	1,001	\$	1,579	\$	4,109
Weighted average number of ordinary shares used in computing basic and diluted net loss per share (1)		8,397,070		7,791,785		7,791,932		7,843,388

(1) See Note 2(m) to our financial statements for the year ended December 31, 2012 for an explanation of the method used to calculate basic and diluted net loss per ordinary share and the weighted average number of shares used in computation of the per share amounts.

(in thousands of U.S. dollars) Balance Sheet Data:	As of Jur Actual	e 30, 2013 As Adjusted (unaudited)(1)		
Total long-term assets	\$ 24	\$ 24		
Total current liabilities	343	343		
Shareholders' equity	21,361	52,081		

(1) The unaudited as adjusted column in the balance sheet data above gives effect to the sale of 2,000,000 ordinary shares in this offering at a public offering price of \$16.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, as if the sale had occurred on June 30, 2013.

#### **RISK FACTORS**

An investment in our ordinary shares involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the consolidated financial statements and the related notes included elsewhere in this prospectus, before deciding whether to invest in our ordinary shares. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our ordinary shares to 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, MG01CI, and we may not obtain regulatory approval of MG01CI 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 MG01CI, 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, MG01CI in a timely manner. The process to develop, obtain regulatory approval for, and commercialize MG01CI 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 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 MG01CI 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 MG01CI. 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 MG01CI. This would reduce our target market and limit the full commercial potential of MG01CI. Many countries are undertaking cost-containment measures that could affect pricing or reimbursement of a product.

#### 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;
- <sup>Ÿ</sup> 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;
- Ϋ́ insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- Ϋ́ 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;
- Ϋ́ 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:

- Ϋ́ 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;
- Ϋ́ unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- $\ddot{Y}$  lack of adequate funding to continue the clinical trial.

# Positive results in previous pre-clinical and clinical trials of MG01CI may not be replicated in future clinical trials of MG01CI, which could result in development delays or a failure to obtain marketing approval.

Positive results in previous pre-clinical and clinical studies of MG01CI 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 MG01CI 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.

# If we in-license molecules or new technologies, this may delay or otherwise adversely affect the development of our existing drug candidates, which may negatively impact our business, results of operations and financial condition.

In addition to our own internally developed MG01CI to treat ADHD and other cognitive dysfunctions, we may seek opportunities to in-license and advance other molecules that can treat cognitive dysfunctions and have value-creating potential to take advantage of our development know-how and experience in this market. If we in-license any additional molecule, our capital requirements may increase significantly. In addition, in-licensing additional molecules may place a strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidate or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may delay the development of our drug candidates and materially and adversely impact our business, results of operations and financial condition.

#### 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 MG01CI for many reasons, including:

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  m Y}$  we may not be able to demonstrate to the satisfaction of the FDA that MG01CI is safe and effective for any indication;
- Ϋ́ the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval;
- Ϋ́ 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 MG01CI's clinical and other benefits outweigh its safety risks;
- Ϋ́ 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 MG01CI 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;
- Ϋ́ 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 Phase 3 clinical trials that will be substantially broader than our Phase 2 trial. We will also need to agree on a protocol with the FDA for the clinical trials before commencing those trials. 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 MG01CI and may be forced to cease operations.

Even if we obtain FDA approval for MG01CI 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 MG01CI, we may be forced to cease operations.

#### Even if MG01CI receives marketing approval, there could be adverse effects not discovered during development.

Even if MG01CI receives marketing approval, we or others may later identify undesirable side effects caused by the product or problems with our thirdparty 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;
- Ý regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- Ϋ́ 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;
- Ϋ́ 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;
- $\ddot{Y}$  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 MG01CI to other cognitive conditions, and ultimate regulatory approval for any additional applications is highly uncertain.

We recently completed a pre-clinical study evaluating MG01CI in a recognized mouse model of Fragile X. In addition, we plan to investigate the use of MG01CI 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 MG01CI 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 MGO1CI 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 MG01CI would be harmed and our ability to generate product revenue would be delayed, possibly materially.

## We may not be able to obtain orphan drug designation for MG01CI 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.

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.

Even if we obtain orphan drug exclusivity for MG01CI to treat Fragile X, that exclusivity may not effectively protect the product from competition because different drugs 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. If any of the above happens, we might not be able to commercialize and generate revenue from using MG01CI to treat Fragile X.

# Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize MG01CI 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 MG01CI or any other product candidate that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell MG01CI 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 MG01CI, 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.

More recently, President Obama signed into law the Patient Protection and Affordable Care Act, 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. 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 MG01CI 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 MG01CI, if it is approved for marketing, may include restrictions on use, such as limitations on how ADHD is defined and diagnosed or limiting MG01CI to second-line or concomitant therapy. In addition, the labeling may include significant restrictions on use. MG01CI 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—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;
- Ϋ́ seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or
- $\ddot{Y}$  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 MG01CI outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If MG01CI is approved for commercialization outside the United States, we will likely enter into agreements with third parties to market MG01CI 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;
- $\ddot{\mathrm{Y}}$  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;
- Ϋ́ workforce uncertainty in countries where labor unrest is more common than in the United States;
- Ϋ́ 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 MG01CI. 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 MG01CI, sales will be limited unless the product achieves broad market acceptance.

The commercial success of MG01CI 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;
- $\ddot{Y}$  the prevalence and severity of any adverse side effects;
- Ÿ limitations or warnings contained in the product's approved labeling;
- Ϋ́ 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 MG01CI, 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 MG01CI 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 MG01CI may include restrictions on use, such as limitations on how ADHD is defined and diagnosed or limiting MG01CI to second-line or concomitant therapy. The FDA may impose further requirements or restrictions on the distribution or use of MG01CI 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 MG01CI, physicians may nevertheless prescribe MG01CI 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 MG01CI if reimbursement for the product is limited.

Market acceptance and sales of MG01CI 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 MG01CI 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 MG01CI, contract manufactures 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 intend to rely primarily on third parties to market and sell MG01CI.

We currently have no manufacturing, sales or distribution capabilities. To the extent we rely on third parties to commercialize MG01CI, if marketing approval is obtained, we may receive less revenue than if we commercialized MG01CI 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 MG01CI, 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, MG01CI 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 MG01CI 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 MG01CI 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 MG01CI. Key competitive factors affecting the commercial success of MG01CI 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 MG01CI 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 MG01CI 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 MG01CI 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 MG01CI 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:

- $\ddot{
  m Y}$  decreased demand for MG01CI 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 MG01CI 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, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for MG01CI 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, MG01CI. We have funded our operations to date primarily through proceeds from the private and public placement 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 six months ended June 30, 2012 and 2013 and full year 2012 was approximately \$1 million, \$1.7 million and \$1.6 million, respectively. As of June 30, 2013, we had an accumulated deficit of \$9.9 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 MG01CI, 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 MG01CI 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, MG01CI, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize, MG01CI. 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 MG01CI;
- Ÿ develop and obtain regulatory approval for registration studies protocols for MG01CI;
- Ÿ subject to successful completion of registration, clinical trials and perhaps additional clinical trials of MG01CI, apply for and obtain marketing approval;
- Ϋ́ contract for the manufacture of commercial quantities of MG01CI 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 MG01CI in the United States and other countries.

Even if MG01CI 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 MG01CI. Our future capital requirements may be substantial and will depend on many factors including:

- Ÿ our clinical trials results;
- $\ddot{\mathrm{Y}}$  the scope, progress, results and costs of researching and developing MG01CI;
- $\ddot{\mathrm{Y}}$  the cost, timing and outcomes of seeking marketing approval of MG01CI;
- 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 MG01CI for the treatment of other conditions;
- <sup>Ÿ</sup> the costs associated with commercializing MG01CI if we receive marketing approval, including the cost and timing of establishing sales, marketing and distribution capabilities to market and sell MG01CI;



- Ÿ the cost of manufacturing MG01CI;
- Ÿ the timing, receipt and amount of sales of, or royalties on, sales of MG01CI, 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
- $\ddot{Y}$  the costs associated with being a public company.

Based on our current operating plan, we anticipate that the net proceeds of this offering, together with 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 MG01CI 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 MG01CI; or
- Ż delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize MG01CI, 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 anticipate reliance on third-party manufacturers for our products.

We do not currently operate manufacturing facilities for clinical production of MG01CI. 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 contract manufacturers 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 MG01CI.

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 MG01CI. In addition, the FDA and other regulatory authorities require that MG01CI be manufacturing processes, including any failure to deliver sufficient quantities of MG01CI in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of MG01CI. 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 MG01CI 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 MG01CI, 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 MG01CI.

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 MG01CI 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 MG01CI 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.

We previously had a collaboration with Teva Pharmaceuticals, Ltd., a large Israeli generic drug manufacturer. After our successful proof of concept trial in 2010, Teva made an equity investment in us, negotiated the right to acquire us should MG01CI reach market, and funded the next stage of clinical development of MG01CI. All of Teva's rights with respect to the development of MG01CI and its right to acquire us terminated when it failed to timely exercise an option to continue financing the development of MG01CI in November 2011. We do not have any continuing obligations to Teva other than that Teva continues to be a shareholder of the Company with related rights.

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 contract research organizations, 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 MG01CI 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 MG01CI. 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. 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 MG01CI 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:

- Ϋ́ any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
- Ϋ́ if we are not issued additional patents or if issued patents expire, there would be no protections against competitors making generic equivalents;
- Ϋ́ there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- Ϋ́ there may be other patents existing in the patent landscape for MG01CI that will affect our freedom to operate;
- Ϋ́ 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
- <sup>Ÿ</sup> 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 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. As a result, 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 MG01CI 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
- <sup>Ϋ́</sup> 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 Vice President CMC (chemistry, manufacturing and controls) & Non-Clinical Development, Ms. Hanna Ron, who has been with us since 2011, and our Vice President, Finance Mr. Nir Peles, who has been with us since 2013. A key consultant is our Chief Financial Officer/Chief Accounting Officer, Udi Gilboa, who co-founded us in 2008 and has been with us since. 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 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 controls over financial reporting are 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 a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls 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 seven employees 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 (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 contract manufacturers, 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 this Offering and Ownership of 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 be difficult 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 offering price 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 MG01CI;
- 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;
- $\ddot{\mathrm{Y}}$  any major changes in our Board of Directors or management; and
- Ÿ legislation in the United States relating to the sale or pricing of pharmaceuticals.

In addition, the stock market in general, and The 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 50% of our outstanding ordinary shares and will own approximately 42% of our ordinary shares upon the closing of this offering. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

After this offering, our two major shareholders will, in the aggregate, beneficially own approximately 42% of our ordinary shares (assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options). 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.

#### If you purchase our ordinary shares in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The offering price is substantially higher than the net tangible book value per share of our ordinary shares. Investors purchasing ordinary shares in this offering will pay a price per share that substantially exceeds the net tangible book value of our ordinary shares. As a result, investors purchasing ordinary shares in this offering will incur immediate dilution of \$12.53 per share, based on a public offering price of \$16.50 per share, and our pro forma net tangible book value as of June 30, 2013. In addition, as of that date, options and warrants to purchase 1,115,466 of our ordinary shares at a weighted average exercise price of \$5.24 per share were outstanding. The exercise of these options and warrants would result in additional dilution. As a result of this dilution, investors purchasing shares in this offering may receive significantly less than the purchase price paid in this offering in the event of liquidation. For more information, please refer to the section of this prospectus entitled "Dilution."

#### 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. Approximately half of the shares owned by our existing shareholders and option holders are subject to lock-up agreements with the underwriters of this offering that restrict the shareholders' ability to transfer our ordinary shares for at least three months from the date of this prospectus. In addition, other existing shareholders and option holders, who held our securities prior to our initial public offering consummated in May 2013, are subject to lock-up agreements that expire no earlier than November 21, 2013. Substantially all of our outstanding shares will become eligible for sale upon expiration of the applicable lockup period, as described in the section of this prospectus entitled "Shares Eligible for Future Sale." In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of shares by these shareholders could have a material adverse effect on the trading price of our ordinary shares.

### Our management will have broad discretion in the use of the net proceeds from this offering and may allocate the net proceeds from this offering in ways that you and other shareholders may not approve.

Our management will have broad discretion in the use of the net proceeds, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure of our management to use these funds effectively could harm our business. Pending their use, our current policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. These investments may not yield a favorable return to our shareholders.

### 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 Exchange Act, the Sarbanes-Oxley Act, the listing requirements of the securities exchange on which our ordinary shares are traded, 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 have 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 recently enacted 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:

- <sup>Ϋ́</sup> 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;
- <sup>Ϋ́</sup> 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;
- 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; and
- Ÿ our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

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 this 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 30<sup>th</sup>, 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.

# Our election to use the extended transition period for complying with new or revised accounting standards under the recently enacted JOBS Act could undermine investor confidence in our company and adversely affect the market price of our ordinary shares.

Our election to use the extended transition period for complying with new or revised accounting standards means that we may delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. This election could undermine investor confidence in our company and adversely affect the market price of our ordinary shares in part because our financial statements may not be comparable to companies that comply with public company effective dates.

### 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. 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 have sometimes declined 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 currently committed to covering the reinstatement value of direct damages that are 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 an economic boycott. 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 condition 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 45 (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 negatively affect us.

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 depreciate relative to the U.S. dollar, or that the inflation rate in Israel would increase materially. 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 2012, approximately 40% of our expenses were denominated in New Israeli Shekel. Changes of 5% and 10% in the USD/NIS exchange rate would have increased/decreased the operation expenses by 2% and 4%, respectively. The exchange rate as of October 23, 2013 was \$1.00 = NIS3.52. 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 MG01CI, 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 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 of this prospectus, we have not been required to pay any royalties with respect to the OCS grants. As of the date of this prospectus, 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:

- Ϋ́no cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates; and
- <sup>Ϋ́</sup> 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 in this prospectus 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. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this prospectus.

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

The liabilities and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and by Israeli law. These liabilities and responsibilities differ in some material respects from the liabilities 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 "Management—Approval of Related Party Transactions under Israeli Law— Shareholder Duties" 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.

# CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus constitute forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" "intends" or "continue," or the negative of these terms or other comparable terminology.

Forward-looking statements include, but are not limited to, statements about:

- Ÿ FDA approval of, or other regulatory action in the U.S. and elsewhere with respect to, MG01CI;
- Ÿ the commercial launch and future sales of MG01CI or any other future products or product candidates;
- Ÿ our ability to achieve favorable pricing for MG01CI;
- Ϋ́ the potential for our drug candidate MG01CI to receive designation as an orphan drug and implications if it does not receive such designation;
- Ÿ our expectations regarding the commercial supply of our MG01CI drug candidate;
- Ÿ third-party payor reimbursement for MG01CI;
- Ϋ́ our estimates regarding anticipated expenses, capital requirements and our needs for additional financing;
- Ÿ the ADHD patient market size and market adoption of MG01CI by physicians and patients;
- $\ddot{Y}$  the timing, cost or other aspects of the commercial launch of MG01CI;
- Ÿ the timing of commencement, duration and cost of clinical trials for MG01CI or whether such trials will be conducted at all;
- Ÿ completion and receiving favorable results of clinical trials for MG01CI;
- Ÿ our use of proceeds from this offering;
- Ÿ issuance of patents to us by the U.S. PTO and other governmental patent agencies;
- Ÿ the development and approval of the use of MG01CI for additional indications other than ADHD and Fragile X; and
- Ÿ our expectations regarding licensing, acquisitions and strategic operations.

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. We discuss many of these risks in this prospectus in greater detail under the heading "Risk Factors" and elsewhere in this prospectus. You should not rely upon forward-looking statements as predictions of future events.

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 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 prospectus.

# PRICE HISTORY OF OUR ORDINARY SHARES

Our ordinary shares have been listed on the NASDAQ Capital Market under the symbol "ADHD" since May 22, 2013. 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:

	Low	High
Quarterly:		
Fourth Quarter (through October 24, 2013)	\$ 14.78	\$ 26.96
Third Quarter	\$ 6.80	\$ 18.99
Second Quarter (beginning May 22, 2013)	\$ 6.50	\$ 8.30
Most Recent Six Months:		
October (through October 24, 2013)	\$ 14.78	\$ 26.96
September	\$ 12.29	\$ 18.99
August	\$ 11.00	\$ 15.83
July	\$ 6.80	\$ 11.45
June	\$ 6.50	\$ 7.38
May (beginning May 22, 2013)	\$ 6.81	\$ 8.30

#### **USE OF PROCEEDS**

We estimate that the net proceeds from our issuance and sale of 2,000,000 shares of our ordinary shares in this offering will be approximately \$30.7 million, based on the offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and offering expenses payable by us. If the representative of the underwriters exercises the over-allotment option in full, we estimate that the net proceeds from this offering will be approximately \$35.4 million, based on the offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and offering expenses payable by us. If \$35.4 million, based on the offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and offering expenses payable by us. We currently expect to use the net proceeds from this offering for:

- <sup>Ϋ́</sup> completing the required advanced clinical trials, that, if successful, would allow us to request drug approval of MG01CI to treat children and adults with Fragile X, estimated at \$14,000,000;
- Ÿ completing necessary preparations and conducting a Phase 3 clinical study in pediatric ADHD for MG01CI, estimated at \$10,000,000; and
- Ÿ the remainder for working capital and general corporate purposes.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the status of and results from our clinical trials, whether or not we enter into strategic collaborations or partnerships, and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering.

We have no current commitments or binding agreements with respect to any material acquisition of or investment in any technologies, products or companies.

# **DIVIDEND POLICY**

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 "Taxation—Israeli Tax Considerations" for additional information.

# CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2013:

- Ÿ on an actual basis;
- <sup>Ϋ́</sup> on a pro forma basis to give further effect to the issuance and sale of 2,000,000 ordinary shares in this offering at a public offering price of \$16.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table in conjunction with the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	June 30,	, 2013
(in thousands, except share and per share data)	 Actual	Pro Forma (unaudited)
Ordinary shares NIS 0.01 par value per share-		
50,000,000 shares authorized at June 30, 2013; 11,128,001 issued shares at June 30, 2013	32	38
Additional paid-in capital	\$ 31,231	\$ 61,945
Deficit accumulated during the development stage	\$ (9,902)	(9,902)
Total shareholders' equity	21,361	52,081
Total capitalization	\$ 21,361	52,081

The number of our ordinary shares to be outstanding immediately after this offering is based on 11,128,001 ordinary shares outstanding as of June 30, 2013. This number excludes:

- Ÿ 900,516 shares issuable upon the exercise of share options outstanding as of October 1, 2013 under our equity incentive plan;
- Ÿ an undertaking to issue options to purchase up to 0.75% of the issued and outstanding shares of the Company issuable to an employee of the Company upon meeting certain milestones (such options, if and when issued, to be subject to a three year vesting schedule); and
- Ÿ 214,950 shares issuable upon the exercise of warrants outstanding as of October 1, 2013.

# DILUTION

If you invest in our ordinary shares, you will experience immediate and substantial dilution to the extent of the difference between the public offering price of our ordinary shares and the pro forma net tangible book value per share of our ordinary shares immediately after the offering.

Our historical net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the actual number of outstanding ordinary shares. The historical net tangible book value of our ordinary shares as of June 30, 2013 was \$21,361,000, or \$1.92 per share.

The pro forma net tangible book value of our ordinary shares as of June 30, 2013 was \$52,081,000, or \$3.97 per share. The pro forma net tangible book value gives effect to the issuance and sale of 2,000,000 ordinary shares in this offering at a public offering price of \$16.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table illustrates this dilution on a per share basis to new investors:

Assumed public offering price per share	\$	16.50
Net tangible book value per share before this offering, as of June 30, 2013	1.92	
Increase in net tangible book value per share attributable to new investors in this offering	2.05	
Pro forma net tangible book value per share after offering		3.97
Dilution in pro forma tangible book value per share to new investors		12.53

If the underwriters' over-allotment option to purchase additional shares from us is exercised in full, and based on a public offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma net tangible book value per share after this offering would be approximately \$4.23 per share, the increase in the pro forma net tangible book value per share attributable to new investors would be approximately \$2.31 per share and the dilution to new investors purchasing shares in this offering would be approximately \$12.27 per share.

The table below summarizes, as of June 30, 2013, on the pro forma basis described above, the number of ordinary shares we issued and sold, the total consideration we received and the average price per share (1) paid by our existing shareholders and (2) to be paid by new investors purchasing our ordinary shares in offering at the public offering price of \$16.50 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Pu	rchased	Total Cons	sideration	Average Price
	Number	Percent	Amount	Percent	Per Share
Existing shareholders	11,128,001	84.8% \$	27,796,000	45.7%	2.50
New investors	2,000,000	15.2% \$	33,000,000	54.3 %	16.50
Total	13,128,001	100.0% \$	60,796,000	100.0 %	4.63

The number of our ordinary shares to be outstanding immediately after this offering is based on 11,128,001 ordinary shares outstanding as of June 30, 2013 and is based on a public offering price of \$16.50 per share.

This number excludes:

- Ϋ 900,516 shares issuable upon the exercise of share options outstanding as of October 1, 2013 under our equity incentive plan;
- Ÿ An undertaking to issue options to purchase up to 0.75% of the issued and outstanding shares of the Company issuable to an employee of the Company upon meeting certain milestones (such options, if and when issued, to be subject to a three year vesting schedule); and
- Ÿ 214,950 shares issuable upon the exercise of warrants outstanding as of October 1, 2013.

To the extent that new options are granted under our equity benefit plans, there will be further dilution to investors purchasing ordinary shares in this offering.

If the underwriters exercise their option to purchase additional ordinary shares in full in this offering, the number of ordinary shares held by new investors will increase to 2,300,000, or 17.1% of the total number of ordinary shares outstanding after this offering and the percentage of ordinary shares held by existing shareholders will decrease to 82.9% of the total ordinary shares outstanding.

# SELECTED FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statements of operations data for the periods of six months ended June 30, 2013 and 2012 and balance sheet data as of June 30, 2013 from our unaudited financial statements included elsewhere in this prospectus and the statements of operations data for the years ended December 31, 2012 and 2011 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

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

(in mousulus of 0.5. donars, except share and per share amounts)	Six months period ended June 30,				Years ended December 31,			
		2013		2012		2012		2011
Statements of Operations Data:								
Research and development expenses	\$	396	\$	632	2	\$ 818	5	\$ 1,822
General and administrative expenses		1,114		356	5	683		2,084
Financial expense, net		206		13	5	78		23
Deemed dividend		-		-	•	-		180
Loss attributable to holders of ordinary shares		1,716		1,001		1,579		4,109
Weighted average number of ordinary shares used in computing basic and								
diluted net loss per share		8,397,070		7,791,785	5	7,791,932		7,843,388
(in thousands of U.S. dollars)				June 30, 2013 Actual	June 30, 2013 As Adjusted (unaudited)(1)			Year Ended cember 31, 2012 Actual
Balance Sheet Data:								
			<b>A</b>	2.4	<b></b>	2.4	<b>A</b>	24
Total long-term assets			\$	24	\$	24	\$	21
Total current liabilities			\$	343	\$	343	\$	768
Shareholders' equity (deficiency)			\$	21,361	\$	52,081	\$	(567)

(1) The As Adjusted column in the balance sheet data above gives effect to the issuance and sale of 2,000,000 ordinary shares in this offering at an assumed public offering price of \$16.50 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

#### Introduction

We are an emerging biopharmaceutical company primarily focused on the development and commercialization of our proprietary drug candidate, MG01CI, to treat Attention Deficit Hyperactivity Disorder, or 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. MG01CI 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 discussions with the U.S. Food and Drug Administration, or FDA, to seek approval, via an Investigational New Drug, or IND, Application submission, to conduct advanced clinical trials in the United States for the use of MGO1CI to treat ADHD in adults. If such FDA approval of our IND Application is granted and if these and any future clinical trials demonstrate the safety and efficacy of MGO1CI, we will seek to obtain marketing approval from the FDA for MG01CI 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 MG01CI 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, MG01CI. As of June 30, 2013, we had an accumulated deficit of \$9.9 million. Our financing activities are described below under "Liquidity and Capital Resources."

#### **Financial Overview**

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

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

	June 30,			December 31,			81,	
(in thousands of U.S. dollars)	2013			2012		2012		2011
Salaries and related personnel expenses	\$	64	\$	31	\$	56	\$	161
Cost to third party clinical consultants and expenses related to conducting								
clinical trials		121		532		663		1,464
Share-based compensation		178		*)		*)		18
Travel expenses		6		39		48		81
Other expenses		27		30		51		98
Total		396		632	\$	818		1,822

\*) Represents an amount less than \$1.

We expect that our research and development expenses will materially increase as we have initiated recently clinical activity and prepare to conduct in clinical trials in MG01CI 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, bookkeeping and facilities costs (including rent expense for our facility in Tel Aviv Israel), and depreciation expenses.

We expect that our general and administrative expenses, such as salaries, accounting and legal fees, will increase because we became recently a U.S. public company.

# **Financial Expense and Income**

Financial expense and income consist of bank fees and other transactional costs, exchange rate differences, financial expenses related to our outstanding convertible notes 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, 2012. 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.

# JOBS Act

On April 5, 2012, the U.S. Congress enacted the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards.

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 system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply for a period of five years following the completion of our initial public offering or until we are no longer an "emerging growth company," whichever is earlier.

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

We account for stock-based compensation in accordance with ASC 718, "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 to 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 (all granted at the IPO date or afterwards) were granted at then Ordinary share's closing price at the date of issuance.

We did not grant options to employees or directors in 2011 and 2012 (other than two grants as stated in Note 9(c) to the financial statements for the year ended December 31, 2012, for which no compensation expense was recorded). For options granted up until December 31, 2010, the fair value of the ordinary shares was based on the application of Option-Pricing Method ("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. Options granted during 2013 were granted at the initial public offering price or the then closing price at the date of issuance.

Under the option-pricing method, 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 Ordinary shareholders. Essentially, the rights of the Ordinary 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 its share in each of these call option rights.

# **Results of Operations**

	June 30,			December 3			31,	
	 2013	20	12		2012		2011	
	 (in thousa	ands US\$)			(in thousa	ands U	U <b>S\$)</b>	
Research and development expenses	\$ 396	\$	632	\$	818	\$	1,822	
General and administrative expenses	 1,114		356		683		2,084	
Operating loss	1,510		988		1,501		3,906	
Financial Expense, net	206		13		78		23	
Net Comprehensive loss	\$ 1,716	\$	1,001	\$	1,579	\$	3,929	
Deemed dividend	-		-		-		180	
Net loss attributable to holders of ordinary shares	\$ 1,716	\$	1,001	\$	1,579	\$	4,109	



# Comparison of the Six Months ended June 30, 2013 to the Six Months ended June 30, 2012 and Year Ended December 31, 2012 to the Year Ended December 31, 2011

#### **Research and development expenses**

Our research and development expenses amounted to \$396,000 for six months ended June 30, 2013, representing a decrease of \$236,000, or 37%, compared to \$632,000 for the six months ended June 30, 2012. The decrease is primarily attributable to a reduction of \$411,000 in expenses to third party clinical consultants and other expenses related to conducting clinical trials. The decrease was offset by an increase of payroll related expenses in an amount of \$33,000 and additional increase of \$178,000 in 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 \$1,114,000 for the six months ended June 30, 2013, representing an increase of \$758,000, or 213%, compared to \$356,000 for the six months ended June 30, 2012. The increase is attributable primarily to an increase of \$103,000 in salaries and related personnel expenses, of \$551,000 in share-based compensation expenses, as well as an increase of \$85,000 in professional services.

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 \$1,508,000 in share-based compensation expenses, an increase of \$113,000 in professional services and an increase of \$52,000 in travel expenses.

#### **Operating loss**

As a result of the foregoing, our operating loss for the six months ended June 30, 2013 was \$1,510,000, as compared to an operating loss of \$988,000 for the six months ended June 30, 2012, an increase of \$522,000, or 52%.

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 \$206,000 for the six months ended June 30, 2013, representing an increase of \$193,000 compared to financial expenses of \$13,000 for the six months ended June 30, 2012. The increase in financial expenses in an amount of \$203,000 is attributable to financial expenses related to the convertible notes which were converted into equity upon our initial public offering.

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.

#### Loss

As a result of the foregoing, our loss for the six months ended June 30, 2013 was \$1,716,000, as compared to \$1,001,000 for the six months ended June 30, 2012, an increase of \$715,000, or 71%.

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%.

# Liquidity and Capital Resources

# Overview

Since our inception through June 30, 2013, we have funded our operations principally with \$27.8 million from the sale of ordinary shares, preferred shares and convertible notes. As of June 30, 2013, we had \$17.6 million in cash and cash equivalents and an additional amount of \$4 million in a short-term deposit.

	Six months Ended, June 30,			Years Ended, December 31,				
		2013		2012		2012	2011	
		(in thousands US\$)				(in thousands US\$)		
Operating activities	\$	(532)	\$	(986)	\$	(1,585) \$	5 (2,361)	
Investing activities		(4,007)		974		1,026	(1,041)	
Financing activities		22,035		-		601	2,620	
Net increase (decrease) in cash and cash equivalents		17,496		(12)		42	(782)	

### **Operating Activities**

Net cash used in operating activities of \$0.5 million during the six months ended June 30, 2013 was primarily used for payment of \$0.1 million for clinical trials and other third party related expenses, \$0.1 million for patent registration and an aggregate of \$0.2 million in salary payments. The remaining amount of \$0.1 million was for travel, rent and other miscellaneous expenses. Net cash used in operating activities of \$1 million during the six months ended June 30, 2012 was primarily used for a payment of \$0.6 million for clinical trials and other third party expenses and an aggregate of \$0.1 million in salary payments. The remaining amount of \$0.3 million was for travel, patent registration, rent and 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 \$4 million during the six months ended June 30, 2013 reflected our use of cash to invest in short-term deposits. Net cash provided by investing activities of \$1 million during the six months ended June 30, 2012 reflected withdrawal of short-term and restricted bank deposits. Net cash used in investing activities during 2011 was \$1 million primarily reflected our use of cash to invest in short-term bank deposits, and increase in restricted bank deposits. In 2012, we withdrew these deposits into cash.

# **Financing Activities**

Net cash provided by financing activities of \$22 million in the six months ended June 30, 2013 consisted of a \$21.9 million issuance of share capital upon initial public offering and \$0.1 million of proceeds from issuance of convertible notes. In the six months ended June 30, 2012 there were no financing activities.

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. 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 June 30, 2013, our cash, cash equivalents and short term deposits totaled \$21.6 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 and the net proceeds from the current offering 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 MG01CI and commercialize the drug. We currently anticipate that, assuming consummation of the current offering, 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:

- Ϋ́ the progress and costs of our pre-clinical studies, clinical trials and other research and development activities;
- Ÿ the scope, prioritization and number of our clinical trials and other research and development programs;
- Ÿ 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;
- Ϋ́ 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;
- Ϋ́ the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally;
- Ý 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.

# **Contractual Obligations**

The following table summarizes our significant contractual obligations at December 31, 2012:

		Less than 1			More than 5		
	Total	year	1-3 years	3-5 years	years		
	(in thousands US\$)						
Operating leases:							
Facility	4	4	-	-	-		
Motor Vehicles	17	14	3	-	-		

During the six months period ended June 30, 2013, and in particular since we completed our initial public offering in May 2013, we initiated our plan to commence an advanced Clinical Trial in adult ADHD. To that end, during such six months period, we engaged with various service providers and vendors. However, we do not deem such engagements as significant compared with our current financial resources.

#### **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.

#### **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 USD, and a certain portion of our expenses is denominated in NIS. For instance, in 2012, approximately 40% of our expenses were denominated in New Israeli Shekel. Changes of 5% and 10% in the USD/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.

# BUSINESS

We are an emerging biopharmaceutical company primarily focused on the development and commercialization of our proprietary drug candidate, MG01CI, to treat Attention Deficit Hyperactivity Disorder, or ADHD, and other potential cognitive dysfunctions including 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. MG01CI is a non-stimulant with a different mechanism of action. MG01CI 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.

We have initiated discussions with the U.S. Food and Drug Administration, or FDA, to seek approval, via an Investigational New Drug, or IND, Application submission, to conduct advanced clinical trials in the United States for the use of MGO1CI to treat ADHD in adults. If such FDA approval of our IND Application is granted and if these and any future clinical trials demonstrate the safety and efficacy of MGO1CI, we will seek to obtain marketing approval from the FDA for MG01CI 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. 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 5% and 12% 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 46% of all adults who had ADHD as children continuing to have symptoms of the disorder as adults. Approximately 95% of these adults experience impaired inattention 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. 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 prescribed with stimulants renew their prescription the following month. There also is a non-stimulant drug on the market called Strattera (Atomoxetine), approved in 2002. This drug also has significant side effects, such as fatigue, decreased appetite, 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 (Intuniv (Guanfacine) and Kapvay (Clonidine)). These two drugs have not been approved for use in adults 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, MG01CI is a non-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. The trial also demonstrated favorable tolerability with no significant side effects over a placebo. MG01CI 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 executive function, we believe that MG01CI possibly may be useful in treating additional cognitive disorders. Accordingly, recently we have completed a pre-clinical study evaluating MG01CI in the standard mouse model of Fragile X (FMR1 knockout mouse). The study showed significant improvement in cognitive and social functioning following treatment with MG01CI in the Fragile X model.

Fragile X, a rare disease, as such term is 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 (macro-orchidism) 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.

The study we completed included multiple behavioral assessments of 40 mice, comprising 20 Fragile X knock-out mice and 20 control littermate mice that were treated with MG01CI 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, 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).

The positive outcomes we reported in this animal model we believe warrant investigation in clinical trials to evaluate the safety and efficacy of MG01CI 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 and other cognitive disorders.

# **About ADHD**

# The ADHD Market

The U.S. ADHD market size in 2011 has been estimated to be \$3.8 billion, which accounted for approximately 90% of the global ADHD market. The difference in market sizes between U.S. and non-U.S. sales does not stem from a difference in sales volumes, but simply the lack of significant sales of innovative ADHD drugs outside the U.S. (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 (CAGR) of 7.3% per annum and reach \$6.2 billion by 2018. The global ADHD market is forecast to grow at a CAGR of 8.0% in part because higher disease recognition is expected in Japan and Europe due to the adoption of the broader diagnostic criteria prevalent in the U.S. Further, these predominant criteria are expected to broaden further in 2013. 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, Intuniv and Kapvay. 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 change 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 46% of adults who suffered from ADHD as children continue to have symptoms of the disorder as adults, with approximately 95% 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

Diagnosis of ADHD

Lower occupational status

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 (DSM-V), diagnostic criteria are most widely used to diagnose ADHD.

Less likely to quit in adulthood

- 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 (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 US\$m	Peak Sales US\$m
Vyvanse (2008)	Lisdexamfetamine	Shire	1,030	1,635 (2016)
Concerta (2000)	Methylphenidate	J&J	1,073	1,326 (2009)
Adderall XR (2001)	Amphetamine	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 non-stimulant 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 that is a non-stimulant. Strattera has been effective, but it also has serious side effects, such as fatigue, decreased appetite, 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. New non-stimulant therapies, such as MG01CI, will not have the risk of abuse and do not have significantly delayed effect, and we believe that their 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 prescriptions re-filled beyond the first month. Therefore, there is a significant need to develop safe and effective non-stimulant 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, computerbased 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 (CAARS). CAARS measure 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 Phase 3 studies of approved pharmacotherapies for ADHD. Modified versions of the CAARS measure are used for diagnostics in children, with a different emphasis on the type of symptoms.
- Ÿ Adult ADHD Quality of Life Questionnaire (AQoL). 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.
- Ÿ 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 subscores for Response Time Variability (a time measurement of how consistently a target signal is identified and a microswitch is pressed throughout the test), Response Time (a time measurement of how fast or slow information is processed and responded to), Commission Errors (a measure of impulsivity: how many times an incorrect signal is identified and the microswitch is pressed erroneously), and Omission Errors (a measure of inattention: how many times is the correct target signal missed and the microswitch 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.</p>

# **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, MG01CI. These trials included:



- Ÿ 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
- Ÿ 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 MG01CI and a matching placebo.

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

	Phase 2a	Phase 2b		
When the clinical study was held	Q1-Q2 2010	Q2-Q3 2011		
How long the clinical study was active	3 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		
Whether we conducted the study with any other parties	No	No		
The steps taken to ensure the accuracy of the results	8	<ul> <li>O) oversight, including monitoring visits; outside</li> <li>ne data management system; automatic and manual</li> <li>v</li> </ul>		

The Phase 2a study was designed to evaluate the effect on cognitive function of a single oral administration of MG01CI 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 highly 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.

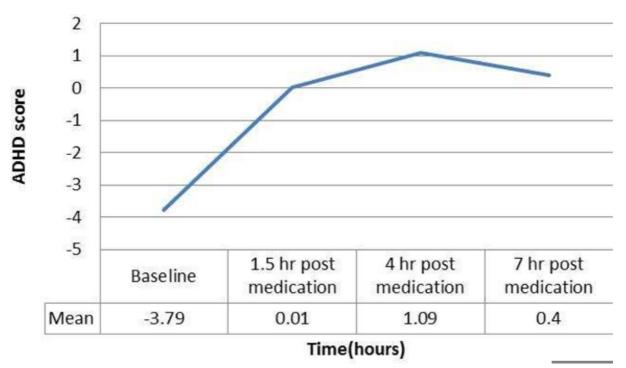
Parameter (n=38)	Change from baseline	р
Omission Score	+12.9 (+16.6%)	p<0.03
Commission Score	+6.9 (+7.5%)	p<0.01
Response Time Score	+12.9 (+12.2%)	p<0.02
Response Time Variability Score	+24.2 (+38.6%)	p<0.001
ADHD Score	+3.9 (+75%)	p<0.001
	TOVA Subscores	

Furthermore, results of the Wechsler subtests confirmed the ability of MG01CI 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	<b>Baseline mean</b>	Post medication mean		
(n-38)	(min,max)	(min,max)	Change	р
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

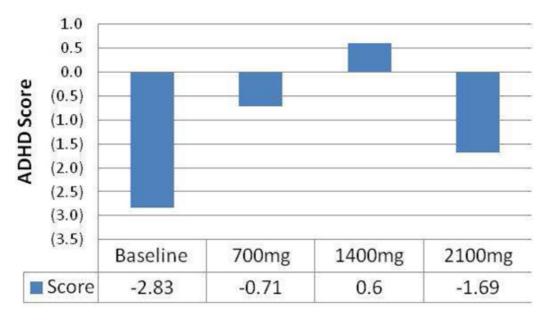
In a small extension study to study the duration of drug benefits, 10 subjects were evaluated using TOVA immediately before, and 90 minutes, 4 hours and 7 hours after, taking a single 1400mg dose of MG01CI. Data below show the mean TOVA scores in these subjects at the specified time points, showing an extended effect of the drug on cognitive functions. A TOVA score of -1.8 or less is considered abnormal.



# Mean ADHD Scores Following Single MG01CI Dosing

In another extension study designed to validate the MG01CI dose used in studies thus far, 10 subjects were evaluated using TOVA 90 minutes after blindly taking either 700mg, 1400mg or 2100mg doses of MG01CI on separate occasions. TOVA results following these treatments were compared to the baseline and 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 MG01CI to be 700-1400mg.

# Mean ADHD Score



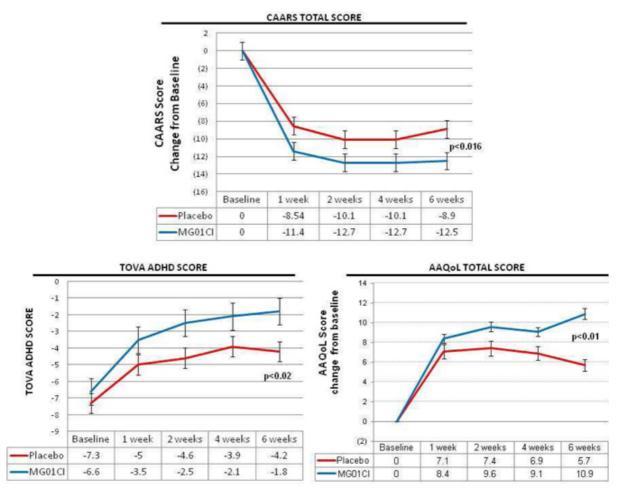


# Summary of Phase 2b Clinical Study

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: 1,400mg MG01CI 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<0.016), TOVA ADHD scores (p<0.02) and AAQoL scores (p<0.01) were observed in the MG01CI 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.



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 MG01CI group and should be considered an anticipated event in future MG01CI research; fatigue occurred in similar numbers in both groups, and headache occurred notably less frequently in the MG01CI group.

### Summary of Clinical Data in ADHD and Key Conclusions

Subjects treated with MG01CI showed statistically significant improvement in CAARS Total ADHD Symptoms Score, as well as higher response rates on the CAARS Total ADHD Symptom Score over subjects treated with placebo.

Improvements in ADHD symptoms (scored by CAARS) were significantly different in subjects treated with MG01Cl vs. placebo as early as two weeks following treatment initiation.

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 this Phase 2b trial of MG01CI. An effect size of 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 Alcobra's Phase 2b study. This effect size is considered large and is in fact comparable to reported effect sizes of stimulant medications.

Statistically significant findings were found using the TOVA neuropsychological test, as well as the Quality of Life questionnaire. TOVA scores were significantly better as early as two weeks after study initiation, and remained significantly better throughout the trial. AAQoL scores were significantly better starting at week six of treatment.

#### Adverse Events

The most commonly reported adverse events in the various clinical studies were nausea, fatigue and headache. Transient moderate nausea, lasting from one to two days, was the only adverse event to occur exclusively in the MG01CI group, with an incidence of approximately 17%; fatigue was largely the same in the control groups (27%) and the MG01CI groups (31%), and headache occurred notably less frequently in the MG01CI group, in about 29% of the subjects, as compared with 38% of the subjects in the placebo group.

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

#### **About Fragile X**

#### **Description of Fragile X**

Fragile X 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 such term is defined by the Orphan Drug Act.



# Fragile X 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, 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 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.

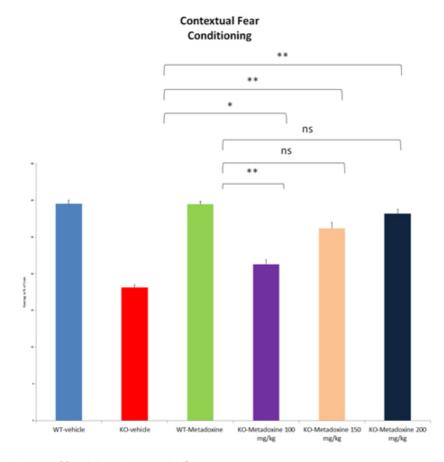
There are several drugs in clinical development for the treatment of Fragile X. FMRP has been shown to serve as a brake to the effects of the metabotropic glutamate receptor 5, or mGluR5, pathway in the brain, and with reduced FMRP in Fragile X, unopposed mGluR5 activation might be responsible for some of the behavioral and cognitive symptoms of Fragile X. Therefore, compounds that, reduce, or antagonize 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. 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 in Fragile X

We recently announced positive findings from a pre-clinical study with a mouse model of Fragile X. Metadoxine, the active ingredient in MG01CI, was shown to have significant findings on behavioral measures in 20 Fragile X knock-out (KO) mice, in which the mouse version of the Fragile X gene is removed. The group of mice included also 20 control littermate mice. The Fragile X 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, and abnormal brain connections, similar findings to those of individuals with Fragile X. In a controlled experiment with Fragile X KO mice and wild type mice given either metadoxine or placebo, significant effects of metadoxine upon Fragile X KO mice were observed on behavioral outcomes, including contextual fear conditioning (a test primarily evaluating memory and learning), social interaction, 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). These findings suggest the potential to translate into a clinical trial of MG01CI in Fragile X. Because of the low prevalence of Fragile X, it is possible to request an orphan drug designation from the FDA. If granted this designation, MG01CI would be eligible for seven years of US marketing exclusivity upon approval of MG01CI for Fragile X and would also be eligible for tax credits related to research and development expenses.

#### 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.



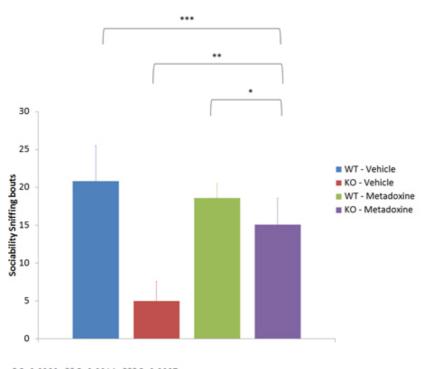
\* p<0.05 \*\* p<0.01 Ns- non significant

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.

# Sociability Sniffing bouts



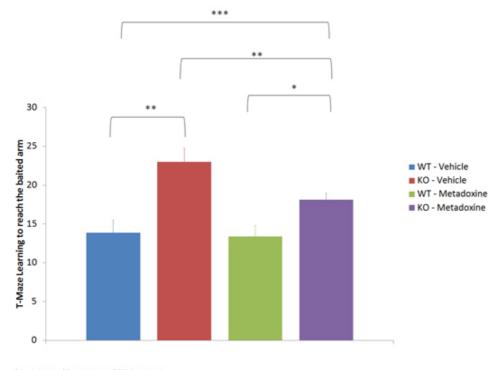
\* P=0.0289, \*\* P=0.0014, \*\*\* P=0.0087

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 brainstructures are also involved.

# T-Maze Learning to reach the baited arm in seconds



<sup>\*</sup> 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.

### **MG01CI Overview and Mechanism of Action**

MG01CI 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-HT2B receptor, thereby reducing binding of other molecules that normally attach there. This protein 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, but no approved or, to our knowledge, investigational drug has yet to display this profile other than ours. MG01CI consists of a single oral tablet, which includes both a rapid onset release Metadoxine formulation and an extended release Metadoxine formulation together providing the desired dual release profile. The new extended-release formulation prolongs the serum 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 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 through blocking the release, delivery and/or the uptake of neurotransmitters by their respective plasma transporters/receptors. All stimulants modulate dopamine and norepinephrine. Atomoxetine (Strattera), the only non-stimulant approved for ADHD in adults, works through modulating norepinephrine. Our recent 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. We found no changes in levels of dopamine, norepinephrine or serotonin in rat brains following administration of MG01CI (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.

The neural networks operating in the brain are directed by various proteins and 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 MG01CI, over 80 different central nervous system 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 network, dopamine network, serotonin network, GABA network, noradrenaline network, opioid network and cannabinoid network. These networks each function to orchestrate different activities and signals in the brain 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 named 5-HT2B that has been implicated genetically in ADHD and molecularly in control of dopamine outflow. 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 absolutely no agonist activities on this receptors. Moreover, no binding was detected to any of the receptors 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 effect and not bind to other receptors where it may have an undesired effect. Therefore, MG01CI 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 recently conducted a study 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.

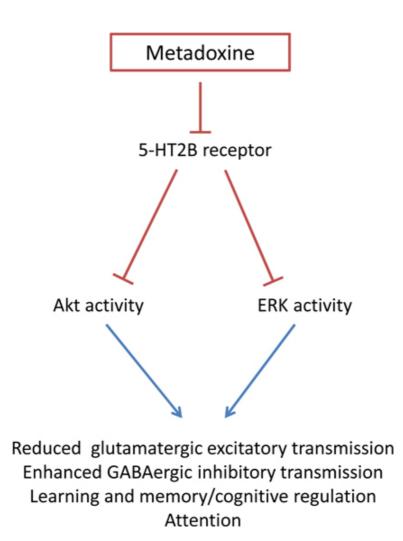
Importantly, improved cognitive function, working memory and social interaction following treatment with Metadoxine (150 mg/kg) in a valid mouse model of Fragile X highly correlated with normalization of biochemical markers reflective of neuronal signaling pathways and oxidative stress measured from whole brain preparations of these animals. Specifically, the increased activation of two regulatory proteins, phospho-ERK1/2 (pERK1/2) and phospho-AKT (pAKT) observed in the affected animals treated only with controls, 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 at all by Metadoxine treatment.

Furthermore, the results of the study showed that affected mice treated with Metadoxine had significantly increased levels of the protein GST when compared to control mice, indicating that treatment with Metadoxine reduces the oxidative damage induced in the Fragile X model. This finding is highly relevant as other oxidative markers in ADHD patients are significantly higher than those of healthy subjects, while antioxidant enzymes such as GST are significantly lower in ADHD patients. Published papers additionally suggest that increased pERK1/2 and pAKT lead to GST inhibition upon oxidative stress, which is mediated by 5-HT2B receptors.

Our working hypothesis is therefore that treatment of metadoxine, a selective antagonist of 5-HT2B receptors may reduce reactive oxygen species and oxidative stress in the brain, increase GST levels, inhibit pAkt and pERK signaling, and thus mediate a potential therapeutic benefit in neuronal impairment by preventing oxidative damage. 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 MG01CI is the first drug candidate to affect the serotonergic pathway and is currently the only drug candidate that shows exclusive antagonistic binding to the 5-HT2B serotonin receptor. Moreover, the 5-HT2B receptor is implicated genetically and physiologically as a possible etiologic factor in the development of ADHD, creating the potential for MG01CI 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 neurotransmitter concentrations or their downstream targets, but rather the disrupted signaling pathways in the cell that may be altered by Metadoxine.

# Metadoxine-mediated intracellular pathways



# **Our Strategy**

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 (MG01CI) and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies for MG01CI for the treatment of ADHD in adults and children. We also plan to advance clinical studies and commercialization plans for MG01CI in additional indications of cognitive dysfunction which present significant market opportunities, such as Fragile X, where we recently announced positive results from pre-clinical study and Shift Work Sleep Disorder. To achieve these objectives, we plan to:

- <sup>Ϋ́</sup> initiate and complete two Phase 3 clinical trials of MG01CI for the treatment of ADHD in adults, and, if they are successful, file for marketing approval for adults in the U.S. (expected initiation before the end of 2013 and expected completion in the second quarter of 2015);
- <sup>Ϋ́</sup> 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 third quarter of 2014 and expected completion of trials in the second 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 (subject to securing additional funding, expected initiation in the first quarter of 2015 for EU and 2016 for Japan and expected completion in the fourth quarter of 2016);
- <sup>Ϋ́</sup> prepare to commercialize MG01CI for the treatment of patients with ADHD by establishing distribution capabilities primarily in conjunction with large pharmaceutical companies;
- <sup>Ÿ</sup> completing the required advanced clinical trials, that, if successful, would allow us to request drug approval of MG01CI to treat children and adults with Fragile X (expected initiation of the first trial in the fourth quarter of 2014 and expected completion thereof in the fourth quarter of 2015); and
- Ý conduct early stage clinical trials into the possible use of MG01CI to treat other cognitive disorders and impairments such as Shift Work Sleep Disorder.

# Commercialization

We do not have any internal sales, marketing or distribution infrastructure. In the event we receive regulatory approval for MG01CI, 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 MG01CI will be made on a plan by plan, and in some cases, patient by patient, basis.

Within the Medicare program, as a self-administered drug, MG01CI 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 MG01CI. 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 six months ended June 30, 2013 to the six months ended June 30, 2012 and years ended December 31, 2012 and 2011, we incurred \$396,000, \$632,000, \$818,000 and \$1,822,000, respectively, of research and development expense.

Our 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 February 2011 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). 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.

After the completion of our initial public offering in May 2013, we accelerated our efforts to initiate a Phase 3 clinical trials in treating adults with ADHD with our MG01CI product candidate. In connection with such efforts we engaged third parties, including a CRO.

# 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 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 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.

#### Former Strategic Relationship with Teva Pharmaceuticals

Following our successful proof of concept trial in 2010, Teva Pharmaceuticals, the large Israeli generic drug company, made an equity investment in us, negotiated the right to acquire us should MG01CI reach the market, and funded the next stage of clinical development of MG01CI. All of Teva's rights to the product terminated when it failed to timely exercise an option to continue development of MG01CI in November 2011 after requesting an extension of the deadline. We do not have any continuing obligations to Teva other than that Teva continues to be a shareholder of the Company with related rights.

#### Manufacturing

We currently have no manufacturing facilities and no personnel with commercial-scale manufacturing experience. We currently rely on one third-party manufacturer, Patheon Inc., which is located in Cincinnati, Ohio, to produce bulk drug substance and drug products required for our clinical trials. 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 current Good Manufacturing Practices, or 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 and biotechnology 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 us. 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 MG01CI. 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 MG01CI. Public announcements regarding the development of competing drugs could adversely affect the price of our stock and the commercial potential of MG01CI.

#### **Intellectual Property**

We seek patent protection in the United States and internationally for MG01CI 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
- Ϋ́ 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.

### **Regulatory Matters**

Clinical trials, the drug approval process, and the marketing of drugs is 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 an Institutional Review Board, 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 MG01CI 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:

- Ÿ nonclinical laboratory and animal tests;
- Ϋ́ submission of an Investigational New Drug, or IND, application which must become effective before clinical trials may begin;
- Ϋ́ adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- Ÿ pre-approval inspection of manufacturing facilities and clinical trial sites; and
- Ϋ́ FDA approval of a new drug application (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 MG01CI 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 MG01CI may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- Ÿ obtaining regulatory approval to commence a study;
- Ÿ reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- Ÿ obtaining institutional review board approval to conduct a study at a prospective site;
- $\ddot{Y}$  recruiting subjects to participate in a study; and
- Ÿ 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 MG01CI and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies. To achieve this objective, we plan to initiate and complete two Phase 3 clinical trials of MG01CI 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 in this prospectus, such as pediatric ADHD and Fragile X.

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

- Ÿ 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.
- Ÿ 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.
- Ÿ 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 MG01CI 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 MG01CI 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 (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 MG01CI.

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 MG01CI, 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**

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 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.

We have applied to receive an Orphan Drug Designation for MG01CI for the treatment of Fragile X in the United States.

## 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

In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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.

#### Employees

As of the date hereof we have seven employees. Our management consists of our chief executive officer, our chief financial and accounting officer, our Chief Medical Officer, our VP for Finance, as well as our VP CMC (chemistry, manufacturing and controls) & Non-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.

# **Property and Facilities**

Our headquarters is currently located in Tel Aviv, Israel and consists of approximately 1900 square feet of leased office space under a lease for three years. We believe that our existing facilities are adequate to meet our current needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

## Legal Proceedings

We are not currently subject to any material legal proceedings.

## MANAGEMENT

## **Executive Officers, Key Employees and Directors**

# **Executive Officers and Directors**

The following table sets forth information regarding our executive officers, key employees and directors as of October 1, 2013:

Name	Age	Position
Dr. Aharon Schwartz	71	Chairman of the Board of Directors
Dr. Yaron Daniely	38	Chief Executive Officer, President and Director
Ehud (Udi) Gilboa	47	Chief Financial Officer, Chief Accounting Officer and Director
Dr. Dalia Megiddo	62	Director
Howard B. Rosen	55	Director
Daniel E. Geffken (1) (2)	56	Director
Ori Mor (1) (2)	43	Director
Dr. Hadas Gelander (1) (2)	47	Director
Dr. Jonathan Rubin	52	Chief Medical Officer
Nir Peles	40	VP for Finance
Hanna Ron	62	VP CMC & Non-Clinical Development

(1) Member of our Audit Committee.

(2) Member of our Compensation Committee.

*Dr. Aharon Schwartz* joined our Board as Chairman in January 2013. 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. 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. 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 the following private companies: Bioblast Ltd. and Samson Neurosciences Ltd. Mr. Gilboa holds a Bachelor's degree and M.B.A. from Tel Aviv University.

*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.

*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. Mr. Rosen was President of ALZA Corporation, a pharmaceutical and medical systems company that merged with Johnson & Johnson, a global healthcare company, in 2001, from 2003 until 2004. 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 AceIRx Therapeutics, Inc. (Nasdaq: ACRX), a company developing products for pain relief, and a number of private biotechnology companies as follows: PavVax, Inc., Entrega, 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.

*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.

*Ori Mor* serves as one of our external directors, a member of our Compensation Committee and the Chairperson of our Audit Committee. Mr. Mor currently serves as the CFO of Medical Compression Systems Ltd. (TASE: MDCL), a leader in innovative, non-invasive solutions for the prevention of venous thromboembolism (VTE). Mr. Mor also serves as an External Director on the Boards of Birman Wood & Hardware Ltd. (TASE: BIRM) and 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. 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, 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 (the "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. Jonathan Rubin*, MD, MBA, 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 BS from Yale University and an MD 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 MBA from Columbia Business School.

*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 BA in economics and accounting from the Hebrew University, an MBA from Tel Aviv University and an MA in law from Bar-Ilan University. Mr. Peles is a certified public accountant in Israel.

Hanna Ron serves as VP CMC and Non-Clinical Development 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 Biolin 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 BSc in Pharmacy from Hebrew University in Jerusalem, an MSc in Pharmaceutical Sciences (Clinical Pharmacy) from the Hebrew University and MSc in Chemical Engineer from School of Engineering Tel Aviv University. She is licensed as a pharmacist, the Ministry of Health, Israel.

## Arrangements Concerning Election of Directors; Family Relationships

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our directors or members of senior management were selected as such. In addition, there are no family relationships among our executive officers and directors.

## **Clinical Advisory Board**

The Company has a Clinical Advisory Board of 10 experts in ADHD. The chairman is Lenard A. Adler, M.D. Dr. Adler has been the Director of the Adult ADHD Program in the Department of Psychiatry at New York University (NYU) School of Medicine in New York since 1995. He is also Professor of Psychiatry and Child and Adolescent Psychiatry at the NYU School of Medicine. Dr. Adler has been a principal contributor to numerous new treatment trials in ADHD and in the development of new scales to diagnose and evaluate symptoms of adult ADHD. He is also author of a book on adult ADHD titled "Scattered Minds." We entered into a consulting agreement with Dr. Adler that provides for hourly and daily consideration for the services provided by him and is terminable by either party upon providing 30 days' written advance notice.

## **Corporate Governance Practices**

As an Israeli company we are subject to various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee, the compensation committee and an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the Listing Rules of the NASDAQ Stock Market and other applicable provisions of U.S. securities laws to which we are subject. Under the Listing Rules of the NASDAQ Stock Market, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Listing Rules of the NASDAQ Stock Market, except for certain matters, including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC. For further information, see "Risk Factors" and "—NASDAQ Listing Rules and Home Country Practices."

Dr. Schwartz, Mr. Rosen, Mr. Geffken, Mr. Mor and Dr. Gelander are independent under Rule 5605(a)(2) to the Nasdaq Listing Rules.

### **Board Practices**

#### **Board of Directors**

Under the Israeli Companies Law, setting up the Company's policy and oversight over 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 shall 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 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:

- Ý the majority voted in favor of election includes a majority of the shares held by non-controlling shareholders who do not otherwise 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
- Ÿ 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, and with respect to the approval of certain extraordinary and interested party transactions by shareholders, any shareholder which has 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) 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 otherwise 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; 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

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 must 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 enacted pursuant to the Companies Laws. 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;

 $\ddot{
m Y}$  – 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 serve as an external director following the 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. This restriction extends 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 regulations promulgated under 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 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 Dr. Aharon Schwartz 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:

- Provide the provided as a state of the provided 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
- Ý 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 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.

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 Nasdaq Marketplace Rules.

Dr. Gelander, Mr. Mor and Mr. Geffken and are independent as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and under the listing standards of the NASDAQ Capital 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 an amendment to the Israeli Companies Law, effective December 12, 2012, 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 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 an office holder 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 an amendment to 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 from the NASDAQ listing requirements related 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 Ehud Gilboa, Dr. Dalia 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:

- $\ddot{Y}$  a person (or a relative of a person) who holds more than 5% of the Company's outstanding shares or voting rights;
- $\ddot{Y}$  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
- $\ddot{Y}$  a member of the Company's independent accounting firm, or anyone on his or her behalf.

Guy Sapir, CPA, 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.

## **NASDAQ Listing Rules and Home Country Practices**

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, 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 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

#### Fiduciary duties of directors and executive officers

The Israeli Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Management— Executive officers and directors" is an office holder under the Israeli Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the Company. The duty of care includes a duty to use reasonable means to obtain:

- Ý information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- Ÿ all other important information pertaining to these actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the Company, and includes a duty to:

- Ÿ refrain from any conflict of interest between the performance of his or her duties to the Company and his or her other duties or personal affairs;
- Ÿ refrain from any activity that is competitive with the Company;
- Ÿ refrain from exploiting any business opportunity of the Company to receive a personal gain for himself or herself or others; and
- Ϋ́ disclose to the Company any information or documents relating to the Company's affairs which the office holder received as a result of his or her position as an office holder.

## Disclosure of Personal Interests of an Office Holder

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:

- $\ddot{Y}$  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, as described above under "—NASDAQ Listing Rules and Home Country Practices—Compensation of officers" and "—NASDAQ Listing Rules and Home Country Practices—Shareholder approval."



Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless a majority of the directors or members of the audit committee have a personal interest in the matter, or unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. Generally, if a majority of the members of the audit committee and/or the board of directors has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee and/or the board of directors on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

### Disclosure of Personal Interests of Controlling Shareholders

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
- <sup>Ŷ</sup> 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, as described above under "NASDAQ Listing Rules and Home Country Practices—Compensation of officers".

## Shareholder Duties

Pursuant to the Israeli Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the Company and other shareholders and to refrain from abusing his or her power in the Company, including, among other things, in voting at the general meeting of shareholders and at class shareholder meetings with respect to the following matters:

- Ÿ an amendment to the Company's articles of association;
- Ÿ an increase of the Company's authorized share capital;
- Ÿ a merger; or
- Ϋ́ approval of interested party transactions and acts of office holders that require shareholder approval.

In addition, a shareholder also has a general duty to refrain from discriminating against other shareholders.

Certain shareholders have a further duty of fairness toward the Company. These shareholders include any controlling shareholder, any shareholder who knows that it has the power to determine the outcome of a shareholder vote or a shareholder class vote and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the Company or other power towards the Company. The Israeli Companies Law does not define the substance of this duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

### Exculpation, Insurance and Indemnification of Directors and Officers

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the Company, in whole or in part, for damages caused to the Company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Israeli Companies Law, a company may indemnify, or undertake in advance to indemnify, an office holder for the following liabilities and expenses, imposed on office holder or incurred by office holder due to acts performed by him or her as an office holder, provided its articles of association include a provision authorizing such indemnification:

- Ý financial liability incurred by or imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the Company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- Ÿ reasonable litigation expenses, including attorneys' fees, incurred by the office holder as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent or as a monetary sanction; and
- Ÿ reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the Company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the Company's articles of association:

- Ÿ a breach of the duty of loyalty to the Company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the Company;
- $\ddot{Y}$  a breach of duty of care to the Company or to a third party; and
- $\ddot{Y}$  a financial liability imposed on the office holder in favor of a third party.

Nevertheless, under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:



- Ÿ a breach of fiduciary duty, except for indemnification and insurance for a breach of the duty of loyalty to the Company in the event office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the Company;
- Ÿ a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- $\ddot{\mathrm{Y}}$  an act or omission committed with intent to derive unlawful personal benefit; or
- $\ddot{Y}$  a fine, monetary sanction, penalty or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders require the approval of the compensation committee, board of directors and, in certain circumstances, the shareholders, as described above under "—NASDAQ Listing Rules and Home Country Practices— Compensation of officers."

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted by the Israeli Companies Law.

We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, we have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

#### **Code of Business Conduct and Ethics**

We adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Business Conduct and Ethics is posted on our website at www.alcobra-pharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of the SEC's Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of such Form 20-F, we will disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

## **Compensation of Executive Officers and Directors**

The aggregate compensation, including share-based compensation, paid by us to our directors and executive officers with respect to the year ended December 31, 2012 was approximately \$500,000. This amount includes approximately \$50,000 set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but 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.

As of October 1, 2013, options to purchase 430,013 ordinary shares issued to our chief executive officer, Dr. Yaron Daniely, were outstanding under our 2010 Incentive Option Plan of which 293,133 were vested.

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

## Employment Agreements with Executive Officers; Consulting and Directorship Services Provided by Directors

We have entered into written employment agreements with our executive officers. These agreements contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. Under current 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. Please see "Risk factors—Risks Relating to Our Business and Industry." for a further description of the enforceability of non-competition clauses. See "Certain Relationships and Related Party Transactions—Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for additional information.

We receive consulting and directorship services from certain of our directors. The amounts payable pursuant to these arrangements have been approved by our Board of Directors and shareholders. See "Certain Relationships and Related Party Transactions—Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for additional information.

### **2010 Incentive Option Plan**

We maintain one equity incentive plan—our 2010 Incentive Option Plan, or our 2010 Plan. As of October 1, 2013, a total of 900,516 shares were reserved for issuance under our 2010 Plan, of which options to purchase 900,516 ordinary shares were issued and outstanding thereunder. Of such outstanding options, options to purchase 515,624 ordinary shares were vested as of October 1, 2013, with a weighted average exercise price of \$0.28 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. 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.

### Certain Relationships and Related Party Transactions

The following is a description of the material terms of those transactions with related parties to which we, or our subsidiaries, are party and which we are required to disclose pursuant to the disclosure rules of the SEC.

# Agreements and Arrangements With, and Compensation of, Directors and Executive Officers

### 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 January 2, 2013. Under the terms of his amended employment agreement, Dr. Daniely is entitled to a gross monthly salary of \$15,000. 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. 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 also contributes 5% and 2.5% of his gross monthly salary towards the manager's insurance policy and study fund, respectively. Dr. Daniely 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.

We granted Dr. Daniely an aggregate of 430,013 options to purchase our ordinary shares, of which 293,133 have vested as of October 1, 2013.

#### 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.

## Services of Dr. Aharon Schwartz as Director and 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 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.

### Employment Agreement with Dr. Jonathan Rubin

We entered into an employment agreement, dated July 25, 2013, with Dr. Jonathan Rubin, our Chief Medical Officer. Under the terms of his employment agreement, Dr. Rubin is entitled to a gross annual salary of \$275,000. In addition, Dr. Rubin will be eligible to receive an annual bonus in an amount of up to 50% of his annual salary, to be determined based on the achievement of certain milestones set by our Board of Directors. In addition, Dr. Rubin receives under the agreement certain other benefits, including reimbursements for continued health, dental and vision coverage, individual life insurance and individual long-term disability insurance, annual contribution to retirement and monthly car allowance. Dr. Rubin's employment engagement is terminable by either party upon 45 days' prior written notice and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

We granted Dr. Rubin 55,640 options to purchase our ordinary shares, none of which have vested as of October 1, 2013 and further undertook to grant him options to purchase up to an aggregate of 0.75% of the issued and outstanding shares of the company, issuable upon meeting certain milestones, and subject to a vesting schedule.

#### **Employment Agreement with Mr. Nir Peles**

We entered into an employment agreement, dated April 8, 2013, with Mr. Nir Peles, our VP for Finance. Under the terms of his employment agreement, Mr. Peles is entitled to a gross monthly salary of NIS 35,000. In addition, Mr. Peles 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. Mr. Peles is also entitled to company contributions equivalent to 7.5%, 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). Mr. Peles also contributes 7% and 2.5% of his gross monthly salary towards the manager's insurance policy and study fund, respectively. Mr. Peles' employment engagement is terminable by either party upon thirty days' prior written notice and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

We granted Mr. Peles 36,431 options to purchase our ordinary shares, none of which have vested as of October 1, 2013.

### Employment Agreement with Ms. Hanna Ron

We entered into an employment agreement, dated June 1, 2013, with Ms. Hanna Ron, for the position of Vice President CMC (chemistry, manufacturing and controls) & Non-Clinical Development. Under the terms of her employment agreement, Dr. Ron is entitled to a gross monthly salary of NIS 30,000. In addition, Dr. Ron receives under the agreement other benefits that are provided for by Israeli law or that are customary for employees of her status in Israel, including the right to use (and all related fixed and variable costs in respect of) a leased car and cellular telephone. Ms. Ron is also entitled to company contributions equivalent to 5%, 8.33%, 2.5%, and 7.5% of her gross monthly salary towards certain pension, severance, disability and tax-advantaged savings funds (known as a manager's insurance policy, severance compensation fund, disability insurance, and a study fund, respectively). Ms. Ron also contributes 5% and 2.5% of her gross monthly salary towards customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

We granted Ms. Ron 20,000 options to purchase our ordinary shares, none of which have vested as of October 1, 2013.

### **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, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. 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."

#### PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our ordinary shares as of October 1, 2013 by:

- Ÿ each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- Ÿ each of our directors and executive officers; and
- Ÿ all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting or investment power with respect to ordinary shares. Ordinary shares issuable under share options or warrants that are exercisable within 60 days after October 1, 2013 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrants but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. Percentage of shares beneficially owned before this offering is based on 11,128,001 shares outstanding on October 1, 2013. The number of ordinary shares deemed outstanding after this offering includes the ordinary shares being offered for sale in this offering but assumes no exercise of the underwriter's over-allotment option.

As of October 1, 2013, there were 19 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. To the best of our knowledge, 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.

	No. of Shares Beneficially Owned Prior to this Offering	Percentage Owned Before this Offering	Percentage Owned After this Offering
Directors and executive officers:			
Dr. Yaron Daniely (1)	293,133	2.6%	2.2%
Daniel E. Geffken	-	-	-
Dr. Hadas Gelander	-	-	-
Udi Gilboa	2,734,927	24.6%	20.8%
Dr. Dalia Megiddo	2,803,817	25.2%	21.4%
Ori Mor	-	-	-
Nir Peles	-	-	-
Hanna Ron	-	-	-
Howard B. Rosen	-	-	-
Dr. Jonathan Rubin	-	-	-
Dr. Aharon Schwartz			
All directors and executive officers as a group (11 persons)	5,831,877	52.4%	44.4%
Holders of more than 5% of our voting securities:			
Hadasit Medical Research Services & Development Ltd.	754,891	6.8%	5.8%
Europa International, Inc. (2)	587,000	5.3%	4.5%

(1) Consists of options currently exercisable or exercisable within 60 days of October 1, 2013 to purchase 293,133 ordinary shares (which have an exercise price of \$0.328 per share and expire in November 15, 2020). Does not include 136,880 options that are time-vested. The options were granted under our 2010 Plan.

(2) Pursuant to Schedule 13G filed with the SEC on May 29, 2013, Europa International, Inc., or Europa, Knoll Capital Management, LP, and Mr. Fred Knoll are beneficial owners and have shared voting power and power of disposition over 587,000 ordinary shares owned by Europa. Knoll Capital Management, LP, of which Mr. Knoll is president, is the investment manager of Europa. We have no information as to the holdings of Europa since May 29, 2013.

# **DESCRIPTION OF SHARE CAPITAL**

The following description of our share capital and provisions of our amended and restated articles of association are summaries and do not purport to be complete.

# General

## **Ordinary Shares**

Immediately prior to the consummation of this offering, our authorized share capital will consist of 50,000,000 ordinary shares, par value NIS 0.01 per share. As of October 1, 2013 there were 11,128,001 shares issued and outstanding.

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. They are not redeemable and do not have any preemptive rights.

#### Warrants

As of October 1, 2013, we had the following warrants outstanding:

- Ÿ Warrants issued to professional advisor. As consideration for certain professional services, on April 2, 2008, we issued to certain advisors warrants to purchase up to 58,700 ordinary shares at an exercise price of \$0.0005 per share. These warrants expire on April 2, 2018.
- Ÿ Warrants issued to initial public offering underwriters. In connection with our initial public offering that was consummated in May 2013, we issued to the underwriters warrants to purchase up to 156,250 ordinary shares, exercisable commencing on May 28, 2014. Of these warrants, 52,083 have an exercise price of \$12 per share and expire on May 28, 2015, 52,083 have an exercise price of \$16 per share and expire on November 28, 2015, and 52,084 have an exercise price of \$20 per share and expire on May 28, 2016.

### Options

As of October 1, 2013, options to purchase 900,516 of our ordinary shares, at a weighted average exercise price of \$3.72 per share, were outstanding under our 2010 Incentive Option Plan.

Of such outstanding options, options to purchase 515,624 of our ordinary shares, with a weighted average exercise price of \$0.28 per share, were vested as of October 1, 2013.

#### **Share History**

The following is a summary of the history of our share capital for the last three years.

Share Options. Since January 1, 2010, we have issued 292,531 ordinary shares upon the exercise of share options.

*February 2010 Preferred B Subscription Agreement*. On February 28, 2010, we closed the February 2010 Preferred B Subscription Agreement, pursuant to which we sold an aggregate of 397,698 series B1 preferred shares at a price of \$2.18, and an aggregate of 128,512 series B2 preferred shares at a price of \$1.75 per share and issued warrants to purchase up to an aggregate of 129,257 series B3 preferred shares with an exercise price of \$2.73 per share, which shall expire immediately prior to the closing of this offering.

*February 2011 Share Purchase Agreement*. On March 24, 2011, we closed the February 2011 Share Purchase Agreement, pursuant to which we sold an aggregate of 304,324 of our ordinary shares at a price of \$11.50 per share.

*Recapitalization and conversion of Preferred Shares to Ordinary Shares*. In connection with the February 2011 Share Purchase Agreement, on March 24, 2011, all classes of preferred shares in the Company's share capital, including all preferred shares issued and outstanding, were converted to ordinary shares on a one for one basis, resulting in a one-class capital structure consisting solely of ordinary shares.

2012 Convertible Notes. During 2012, we issued convertible notes for a total principal amount of \$600,000. In accordance with the terms of the convertible notes, the total amount, bearing an annual interest rate of 6%, was automatically converted in the course of our initial public offering into 104,094 ordinary shares, reflecting, at a price of \$6 per share, a 25% discount from the initial public offering price.

2013 Convertible Notes. In February 2013 we issued to certain of our existing shareholders additional convertible notes for an aggregate principal amount of \$115,000. Like the 2012 Convertible Notes, these notes bore an annual interest rate of 6% and were automatically converted in the course of our initial public offering into 19,459 ordinary shares at a 25% discount from the initial public offering price.

*May 2013 Bonus Share Allocation.* On May 19, 2013, we issued additional ordinary shares to all of our shareholders, on a basis of 4.87 bonus shares for each ordinary share outstanding (equivalent to a 5.87-for-1 stock split).

*May 2013 Initial Public Offering.* On May 28, 2013, we closed our initial public offering, pursuant to which we sold an aggregate of 3,125,000 ordinary shares at a price of \$8 per share. The ordinary shares were issued pursuant to the filing, under the Securities Act, of a registration statement on Form F-1, which became effective on May 21, 2013, and the prospectus dated as of May 21, 2013 contained in such registration statement. In connection with the offering, we also issued to the underwriters of the offering warrants to purchase a total of 156,250 ordinary shares at an average exercise price of \$16 per share.

*May 2013 Exercise of Warrants*. In connection with our initial public offering, warrants to purchase up to 129,255 ordinary shares, which were otherwise to expire immediately prior to closing of the offering, were exercised on a cashless basis into 85,192 ordinary shares.

### **Voting Rights**

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting.

### **Transfer of Shares**

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Our research and development efforts were financed in part, in the past, through grants that we received from Israel's Office of the Chief Scientist of the Ministry of Industry, Trade and Labor, as a result of which we must comply with the requirements of the Research Law. According to the Research Law, a change of control of our company should be reported to the research committee at the Ministry of Industry, Trade and Labor, or the Committee, and a change in the holding of the means of control in our company (means of control include the right to vote at a general meeting of a company or a corresponding body of another corporation or the right to appoint directors of the corporation or its general manager) which results in any person not being a citizen or resident of Israel or corporation incorporated in Israel holding 5% or more of the issued share capital or of the voting power of our company, should be reported to the Committee, which may notify us of its objection to such change, and such person shall be required to sign an undertaking in a certain form published by the Committee.

## **Election of Directors**

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors described under "Management—External directors."

Our directors hold office for their scheduled term unless they are removed from office upon the occurrence of certain events, 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 to fill vacancies on the Board of Directors to serve until the next annual meeting following his or her appointment. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Israeli Companies Law. See "Management—Board Practices—External Directors."

#### **Dividend and Liquidation Rights**

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the Company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our Board of Directors.

Pursuant to the Israeli Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, as such items are defined under the Companies Law, according to our then last reviewed or audited financial reports, provided that the date of the financial reports is not more than six months prior to the date of distribution, or we may distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to pay a dividend if our Board of Directors or the court, as applicable, determined that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

### **Exchange Controls**

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

# **Shareholder Meetings**

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our Board of Directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law provides that our Board of Directors is required to convene a special meeting upon the written request of (i) any two of our directors or one-quarter of our Board of Directors, or (ii) one or more shareholders holding, in the aggregate, either (a) 5% of our outstanding issued shares and 1% of our outstanding voting power, or (b) 5% of our outstanding voting power.

Subject to the provisions of the Israeli Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may generally be between four and 40 days prior to the date of the meeting. Furthermore, the Israeli Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- Ÿ amendments to our amended and restated articles of association;
- Ÿ appointment or termination of our auditors;
- Ÿ appointment of external directors;
- Ÿ approval of acts and transactions involving related parties, as defined by the Israeli Companies Law;
- Ÿ increases or reductions of our authorized share capital; and
- Ÿ a merger.

The Israeli Companies Law and our amended and restated articles of association require that a notice of any annual general meeting or special shareholders meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes matters upon which shareholders may vote by means of a voting deed, including the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Under the Israeli Companies Law and our amended and restated articles of association, our shareholders are not permitted to take action via written consent in lieu of a meeting.

### **Voting Rights**

#### Quorum Requirements

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.

#### Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law or by our amended and restated articles of association. Under the Israeli Companies Law certain actions require a special majority, which may include (i) appointment of external directors, requiring the approval described above under "Management—Board Practices— External Directors", (ii) approval of an extraordinary transaction with a controlling shareholder and the terms of employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative (even if not extraordinary), requiring the approval described above under "Approval of Related Party Transactions under Israeli Law—Disclosure of Personal Interests of Controlling Shareholders.", and (iii) approval of a compensation policy, approval of executive officer compensation inconsistent with our office holder compensation policy, compensation of our chief executive officer, or the compensation of an executive officer who is also the controlling shareholder of our company (including an affiliate thereof), all of which require the approval described above under "Management—NASDAQ Listing Rules and Home Country Practices—Compensation of Officers." Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations of any class of our share capital requires a decision of the Board of Directors, and a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting.

Further exceptions to the simple majority vote requirement are a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the Company pursuant to Section 350 of the Israeli Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Israeli law provides that a shareholder of a public company may vote in a meeting and in a class meeting by means of a voting deed in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- Ÿ appointment or removal of directors;
- Ÿ approval of transactions with office holders or interested or related parties;
- Ÿ approval of a merger;
- Y authorization of the chairman of the board or a relative thereof to assume the role or responsibilities of our chief executive officer, and authorization of our chief executive officer or a relative thereof to assume the role or responsibilities of the chairman of the board;
- Ϋ́ approval of an arrangement or reorganization of the Company pursuant to Section 350 of the Israeli Companies Law; and
- Ý other matters in respect of which there is a provision in the articles of association providing that decisions of the general meeting may also be passed by voting deed or which may be prescribed by Israel's Minister of Justice.

The provision allowing the vote by voting deed does not apply if, to the best knowledge of the Company at the time of calling the general shareholders meeting, a controlling shareholder will hold on the record date for such shareholders meeting, voting power sufficient to determine the outcome of the vote.

The Israeli Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the Company and its other shareholders, including voting at general meetings, must act in good faith and in a customary manner, and avoid abusing his or her power. See "Approval of Related Party Transactions under Israeli Law—Shareholder Duties" above for further detail.

#### Access to Corporate Records

Under the Israeli Companies Law and our amended and restated articles of association, shareholders are provided access to the following corporate records: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may submit a reasoned request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been submitted in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

# Modification of Class Rights

The rights attached to any class of shares, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association.

### Acquisitions under Israeli Law

## Full Tender Offer

A person wishing to acquire shares of a public Israeli company and who could as a result hold over 90% of the target company's issued and outstanding share capital or voting rights is required by the Israeli 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 a public Israeli company and who could as a result hold over 90% of the issued and outstanding share capital or voting rights of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding share capital and voting rights of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved it, which condition shall not apply if, following consummation of the tender offer, the acquirer would hold at least 98% of all of the company's outstanding shares and voting rights (or shares and voting rights of the consideration for the acquisition. Even shareholders who indicated their acceptance of the tender offer may so petition the court, unless the acquirer stipulated that a shareholder that accepts the offer may not seek appraisal rights). If the shareholders who did not accept the tender offer hold 5% or more of the issued and outstanding share capital or voting rights of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or voting rights of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or voting rights of the applicable class, from shareholders who accepted the tender offer.

## **Special Tender Offer**

The Israeli Companies Law provides that an acquisition of shares of a public Israeli company must be made by means of a special tender offer if as a result of the acquisition the purchaser could become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Israeli Companies Law (as described below) is met. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Israeli Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser could 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, unless one of the exemptions in the Israeli Companies Law is met. Such exemptions include (a) acquisition of shares issued in the course of a private placement approved by the general meeting of the company as a private placement intended to provide purchaser with holdings of 25% or more of the voting rights in the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if there is no other shareholder of the company, if the company, if there is no other shareholder of the company, if there is no other shareholder of the company, who holds more than 45% of the voting rights in the company, if there is no other shareholder of the company, if there is no other shareholder of the company, or as a private placement intended to provide purchaser with holdings of more than 45% of the voting rights in the company, if there is no other shareholder of the company of

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A 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 number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (disregarding holders who have a personal interest).

If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into 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 Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described above in this prospectus under "Management—NASDAQ Listing Rules and Home Country Practices—Shareholder Approval.")

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve 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 value of the parties to the merger and the consideration offered to the shareholders of the company that have petitioned the court to approve the merger.

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 any of the parties to the merger, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

### Anti-takeover Measures under Israeli Law

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the closing of this offering, no preferred shares will be authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israeli Companies Law as described above in "—Voting Rights."

### **Borrowing Powers**

Pursuant to the Israeli Companies Law and our amended and restated articles of association, our Board of Directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

#### **Changes in Capital**

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law and must be approved by a resolution duly passed by our shareholders at a general meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits and an issuance of shares for less than their nominal value, require the approval of both our Board of Directors and an Israeli court.

## **Transfer Agent**

Our transfer agent in the United States is Continental Stock Transfer & Trust Company.

## SHARES ELIGIBLE FOR FUTURE SALE

Our ordinary shares trade on the NASDAQ Capital Market. However, a liquid trading market for our ordinary shares may not be sustained after this offering. Future sales of substantial amounts of our ordinary shares following this offering, or the perception that these sales could occur, could adversely affect prevailing market prices of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities.

Upon the closing of this offering, we will have outstanding an aggregate of 13,128,001 ordinary shares, assuming (i) the representative of the underwriters does not exercise the over-allotment option, and (ii) no options or warrants outstanding as of October 1, 2013 are exercised.

Of the shares to be outstanding immediately after the closing of this offering, we expect that 7,589,257 shares, including the 2,000,000 shares to be sold in this offering, at the public offering price of \$16.50 per share, will be freely tradable without restriction under the Securities Act, unless owned by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining ordinary shares will be held by our existing shareholders. Because substantially all of these shares were sold outside the United States to persons residing outside the United States at the time, they also will be freely tradable without restriction or further registration, except that shares held by affiliates must be sold under Rule 144, and except for the lock-up restrictions described below. Further, a substantial number of our outstanding shares is subject to the lock-up agreements.

#### Lock-up agreements

#### Lock-up in connection with our initial public offering

We, all of our directors and executive officers and holders of all of our outstanding ordinary shares signed lock-up agreements pursuant to which, subject to certain exceptions, they agreed not to sell or otherwise dispose of their ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of at least 180 days after the date of the pricing of our initial public offering without the prior written consent of Aegis Capital Corp, which consent was granted in order for us to complete this offering.

## Lock-up in connection with this offering

We and our directors and executive officers have signed lock-up agreements pursuant to which, subject to certain exceptions, they have agreed not to sell or otherwise dispose of their ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of 90 days after the date of this prospectus without the prior written consent of Stifel, Nicolaus & Company, Incorporated.

### Rule 144

In general, under Rule 144, any person who is not our affiliate (and has not been an affiliate of ours for the last three months) and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction. In addition, under Rule 144, any person who is not an affiliate of ours (and has not been an affiliate of ours for the last three months) and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

A person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- Ÿ one percent of the number of ordinary shares then outstanding, which will equal 131,280 shares; or
- Ÿ the average weekly trading volume of our ordinary shares on the NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.
- If an affiliate acquires "restricted securities," those securities will also be subject to holding period requirements.

Substantially all of our outstanding ordinary shares are either unrestricted or are eligible for sale under Rule 144. We cannot estimate the number of our ordinary shares that our existing stockholders will elect to sell.

#### Form S-8 Registration Statements

Following the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register up the ordinary shares issued or reserved for issuance under our 2010 Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option and registered under the Form S-8 registration statement will, subject to vesting and lock-up provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to a lock-up, in which case, immediately after the term of the lock-up expires.

# TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction.

# ISRAELI TAX 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 25% (26.5% as of 2014).

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 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 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.

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# 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, 25% in 2013 and 26.5 as of 2014 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.

In addition, a sale of securities may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the U.S.-Israel Income Tax Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the ordinary shares as a capital asset and is entitled to claim the benefits afforded to such a resident by the U.S.-Israel Tax Treaty (called a "Treaty U.S. Resident") is generally exempt from Israeli capital gains tax unless (i) such Treaty U.S. Resident is an individual and was present in Israel for more than 183 days during the relevant taxable year; (ii) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the 12 month period preceding such sale, exchange or disposition, subject to certain conditions; or (iii) the capital gains arising from such sale, exchange or disposition are attributable to a permanent establishment of the Treaty U.S. Resident located in Israel. In any such case, the sale, exchange or disposition of ordinary shares would be subject to Israeli tax, to the extent applicable.

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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.

## Israeli Transfer Pricing Regulations

On November 29, 2006, Income Tax Regulations (Determination of Market Terms), 2006, promulgated under Section 85A of the Tax Ordinance, came into force (the "TP Regulations"). Section 85A of the Tax Ordinance and the TP Regulations generally require that all cross-border transactions carried out between related parties will be conducted on an arm's length principle basis and will be taxed accordingly. We follow that rules where applicable.

# EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR ISRAELI TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR ORDINARY SHARES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

# **U.S. FEDERAL INCOME TAX CONSEQUENCES**

Except as specifically set forth below, the following discussion is limited to the material U.S. federal income tax consequences relating to the purchase, ownership and disposition of our ordinary shares by U.S. Holders (as defined below) that purchase ordinary shares pursuant to the offering and hold such ordinary shares as capital assets. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain former citizens or residents of the United States, persons who hold ordinary shares as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment, persons that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities, and investors in such pass-through entities). Except as expressly set forth herein, this discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of ordinary shares that is, for U.S. federal income tax purposes, (i) an individual who is a citizen or resident of the United States, (ii) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity treated as a partnership for U.S. federal income tax purposes holds the ordinary shares, the U.S. federal income tax consequences relating to an investment in the ordinary shares will depend in part upon the status and activities of such entity and the particular partner. Any such entity should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of the ordinary shares.

Persons considering an investment in the ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of the ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

# Distributions

Subject to the discussion below under "Passive foreign investment company consequences," a U.S. Holder that receives a distribution with respect to an ordinary share generally will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Israeli tax withheld from such distribution) when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's ordinary shares. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's shares, the remainder will be taxed as capital gain. Because we do not account for our income in accordance with U.S. federal income tax purposes, U.S. Holders should expect all distributions to be reported to them as dividends.

The U.S. dollar value of any distribution on the ordinary shares made in NIS generally should be calculated by reference to the exchange rate between the U.S. dollar and the NIS in effect on the date of receipt of such distribution by the U.S. Holder regardless of whether the NIS so received is in fact converted into U.S. dollars at that time. If the NIS so received is converted into U.S. dollars on the date of receipt, such U.S. Holder generally should not recognize currency gain or loss on such conversion. If the NIS so received is not converted into U.S. dollars on the date of receipt, such U.S. Holder generally will have a basis in such NIS equal to the U.S. dollar value of such NIS on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of such NIS by such U.S. Holder generally will be treated as ordinary income or loss and generally will be income or loss from sources within the United States for U.S. foreign tax credit purposes.

Distributions on the ordinary shares that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes. Such dividends will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Distributions treated as dividends that are received by non-corporate U.S. Holders before January 1, 2013 are expected to qualify for the 15% reduced maximum tax rate available for dividends received from "qualified foreign corporation" provided certain holding periods and other requirements are met. Absent a change in current law, dividends received by a U.S. Holder from us on or after January 1, 2013, will be taxed at regular ordinary income tax rates. We will not be treated as a qualifying foreign corporation, and therefore the reduced maximum tax rate in effect for 2012 described above will not apply, if we are a PFIC for the taxable year in which the dividend is paid or the preceding taxable year (see "Passive foreign investment company consequences," below).

Distributions may be subject to Israeli withholding tax—see—"Taxation—Israeli tax considerations—Taxation of our shareholders—Taxation of non-Israeli shareholders on receipt of dividends." Subject to certain conditions and limitations, Israeli taxes withheld from distributions by us may be credited against a U.S. Holder's U.S. federal income tax liability or, alternatively, deducted to determine the U.S. Holder's taxable income. This election to deduct foreign income taxes is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Holder that year. Dividends paid on the ordinary shares generally will constitute income from sources outside the United States and be categorized as "passive category income" for U.S. foreign tax credit purposes.

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## Sale, exchange or other disposition of the ordinary shares

Subject to the discussion below under "Passive foreign investment company consequences," a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of a ordinary share in an amount equal to the difference, if any, between the amount realized (i.e., the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ordinary share, both amounts determined in U.S. dollars. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders (currently a maximum of 15% and increasing to a maximum of 20% after January 1, 2013) or loss if, on the date of sale, exchange or other disposition, the ordinary share was held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of our ordinary shares will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

A U.S. Holder that receives NIS from the sale, exchange or other disposition of ordinary shares will generally realize an amount equal to the U.S. dollar value of the NIS received at the spot rate on the date of sale (or, in the case of cash basis and electing accrual basis U.S. Holders, the settlement date). A U.S. Holder will recognize foreign currency gain or loss to the extent the U.S. dollar value of the amount received at the spot exchange rate on the settlement date differs from the amount realized. A U.S. Holder will have a tax basis in the NIS received equal to its U.S. dollar value on the settlement date. Any gain or loss on a subsequent conversion or other disposition of the NIS will be U.S. source ordinary income or loss.

## Passive foreign investment company consequences

In general, a corporation organized outside the United States will be treated as a PFIC in any taxable year in which either (i) at least 75% of its gross income is "passive income" or (ii) on average at least 50% of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. The average percentage of a corporation's assets that produce or are held for the production of passis of the fair market value of the corporation's assets at the end of each quarter. This determination is based on the adjusted tax basis of the corporation's assets however, if the corporation is a "controlled foreign corporation", that is not a publicly traded corporation for the taxable year. In determining whether a foreign corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we can not rule out a PFIC designation. Nevertheless, because this determination is made annually after the close of each taxable year, because we hold and expect to continue to hold following this offering a substantial amount of cash and cash equivalents, and because the calculation of the value of our assets may be based in part on the value of our ordinary shares, which may fluctuate after this offering and may fluctuate considerably given that market prices of technology companies historically often have been volatile, it is difficult to predict whether we will be a PFIC in any taxable year. Even if we determine that we are not a PFIC after the close of our taxable year, there can be no assurance that the Internal Revenue Service, or the IRS, will agree with our conclusion.

If we are a PFIC in any taxable year during which a U.S. Holder owns ordinary shares, such U.S. Holder could be liable for additional taxes and interest charges upon (i) certain distributions by us (generally any distribution paid during a taxable year that is greater than 125 percent of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for our ordinary shares), and (ii) 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. In these circumstances, the tax will be determined by allocating such distributions or gain ratably over the U.S. Holder's holding period for the ordinary shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years, and an interest charge, generally that applicable to underpayments of tax, will be added to the tax. If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we will generally continue to be treated as a PFIC with respect to the holder for all succeeding years during which the U.S. Holder holds ordinary shares even if we cease to meet the requirements for PFIC status.



The tax consequences that would apply if we were a PFIC would be different from those described above if a timely and valid "mark-to-market" election is made by a U.S. Holder for our ordinary shares. An electing U.S. Holder generally would take into account as ordinary income each year, the excess of the fair market value of our ordinary shares held at the end of the taxable year over the adjusted tax basis of such ordinary shares. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the amount previously included in income as a result of the mark-to-market election. The U.S. Holder's tax basis in our ordinary shares would be adjusted to reflect any income or loss resulting from the mark-to-market election. Any gain from a sale, exchange or other disposition of the ordinary shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any realized gain or loss would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only if the ordinary shares are considered "marketable stock". Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Our ordinary shares will be marketable stock as long as they remain listed on the NASDAQ Global Market and are regularly traded. A mark-to-market election will not apply to our ordinary shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any subsidiary that we own.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. Holder were able to make a valid "qualified electing fund" ("QEF") election. As we do not expect to provide U.S. Holders with the information required in order to permit a QEF election, prospective investors should assume that a QEF election will not be available.

If we are a PFIC in any taxable year during which a U.S. Holder owns the ordinary shares, such U.S. Holder may also suffer adverse tax consequences under the PFIC rules described above with respect to any lower-tier PFIC in which we have a direct or indirect equity interest.

Each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the purchase, ownership and disposition of ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares.

# Certain reporting requirements with respect to payments of Offer Price

U.S. Holders paying more than U.S. \$100,000 for ordinary shares generally will be required to file IRS Form 926 reporting the payment of the Offer Price for an ordinary share to us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. Each U.S. Holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

# Information reporting and backup withholding

Dividends on and proceeds from the sale or other disposition of the ordinary shares may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if (i) the holder fails to provide an accurate taxpayer identification number or otherwise establish a basis for exemption, or (ii) is described in certain other categories of persons. Backup withholding is not an additional tax.

Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

For taxable years beginning after March 18, 2010, new legislation requires certain U.S. Holders who are individuals to report information relating to stock of a non-U.S. person, subject to certain exceptions (including an exception for stock held in custodial accounts maintained by a U.S. financial institution). U.S. Holders are urged to consult their tax advisers regarding the effect, if any, of this legislation on their ownership and disposition of ordinary shares.

# THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

## UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, each of the underwriters named below has severally agreed to purchase from us the aggregate number of ordinary shares set forth opposite their respective names below:

	Number
Underwriters	of Shares
Stifel, Nicolaus & Company, Incorporated	880,000
Aegis Capital Corp.	720,000
JMP Securities LLC	400,000
Total	2,000,000

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The nature of the underwriters' obligations commits them to purchase and pay for all of the ordinary shares listed above if any are purchased. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriting agreement provides that we will indemnify the underwriters against liabilities specified in the underwriting agreement under the Securities Act, or will contribute to payments that the underwriters may be required to make relating to these liabilities.

The underwriters expect to deliver the ordinary shares to purchasers on or about October 30, 2013.

# **Over-Allotment Option**

We have granted a 30-day over-allotment option to the underwriters to purchase up to a total of additional ordinary shares from us, at the public offering price, less the underwriting discounts and commissions payable by us, as set forth on the cover page of this prospectus. If the underwriters exercise this option in whole or in part, then each of the underwriters will be separately committed, subject to the conditions described in the underwriting agreement, to purchase the additional ordinary shares in proportion to their respective commitments set forth in the table above. We will pay the expenses associated with the exercise of the over-allotment option.

# Lock-Up Agreements

We and the holders (including all of our directors and executive officers) of 10% or more of our ordinary shares outstanding prior to this offering have agreed that, without the prior written consent of Stifel, Nicolaus & Company, Incorporated, we and they will not directly or indirectly:

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- offer, sell, contract to sell (including any short sale), pledge, hypothecate, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, grant any option, right or warrant for the sale of, purchase any option or contract to sell, sell any option or contract to purchase, or otherwise encumber, dispose of or transfer, or grant any rights with respect to, directly or indirectly, any ordinary shares or securities convertible into or exchangeable or exercisable for any ordinary shares;
- enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares, whether any such transaction is to be settled by delivery of the ordinary shares or other securities, in cash or otherwise; or
- publicly disclose the intention to do any of the foregoing,

for a period of 90 days after the date of this prospectus. However, in the case of our officers, directors and stockholders, these lock-up restrictions will not apply to:

- bona fide gifts made by the holder;
- to a family member or a trust for the benefit of the undersigned or a family member;
- to a beneficiary pursuant to a will or other testamentary document or applicable laws of descent;
- to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the holder or the immediate family of the holder.

Stifel, Nicolaus & Company, Incorporated, in its sole discretion, may release the ordinary shares and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. When determining whether or not to release ordinary shares and other securities from lock-up agreements, Stifel, Nicolaus & Company, Incorporated will consider, among other factors, the holder's reasons for requesting the release, the number of ordinary shares and other securities for which the release is being requested and market conditions at the time.

# **Commissions and Expenses**

The underwriters propose to offer the ordinary shares directly to the public at the public offering price set forth on the cover page of this prospectus, and at this price less a concession not in excess of \$0.594 per ordinary share to other dealers specified in a master agreement among underwriters who are members of the Financial Industry Regulatory Authority, Inc. After this offering, the offering price, concessions, and other selling terms may be changed by the underwriters. Our ordinary shares are offered subject to receipt and acceptance by the underwriters and to certain other conditions, including the right to reject orders in whole or in part.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us:

		Total			
	Per		Without		With
	Share	Ov	er-Allotment	Ov	er-Allotment
Public offering price	\$ 16.50	\$	33,000,000	\$	37,950,000
Underwriting discounts and commissions	\$ 0.99	\$	1,980,000	\$	2,277,000
Proceeds, before expenses, to us	\$ 15.51	\$	31,020,000	\$	35,673,000

Pursuant to the terms of the underwriting agreement, we have also agreed to reimburse the underwriters for certain expenses, including reasonable fees and expenses of counsel, relating to certain aspects of this offering that will not exceed \$20,000.

We estimate that the total expenses of the offering payable by us, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately \$0.3 million.

# **Indemnification of Underwriters**

We will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.



# NASDAQ Capital Market Listing

Our ordinary shares are listed on The NASDAQ Capital Market under the symbol "ADHD."

## Short Sales, Stabilizing Transactions and Penalty Bids

In order to facilitate this offering, persons participating in this offering may engage in transactions that stabilize, maintain, or otherwise affect the price of ordinary shares during and after this offering. Specifically, the underwriters may engage in the following activities in accordance with the rules of the Securities and Exchange Commission.

Short sales. Short sales involve the sales by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their over-allotment option to purchase shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are any short sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering.

*Stabilizing transactions.* The underwriters may make bids for or purchases of the shares for the purpose of pegging, fixing, or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

*Penalty bids.* If the underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering. Stabilization and syndicate covering transactions may cause the price of the shares to be higher than it would be in the absence of these transactions. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages re-sales of the shares.

The transactions above may occur on The NASDAQ Capital Market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. If these transactions are commenced, they may be discontinued without notice at any time.

#### **Discretionary Sales**

The underwriters have informed us that they do not expect to confirm sales of ordinary shares offered by this prospectus to accounts over which they exercise discretionary authority without obtaining the specific approval of the account holder.

# **Electronic Distribution**

A prospectus in electronic format may be made available on the internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's web site and any information contained in any other web site maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

## Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have in the past provided, and may in the future from time to time provide, investment banking and other financing and banking services to us, for which they have in the past received, and may in the future receive, customary fees and reimbursement for their expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities may involve our securities and instruments.

# **European Economic Area**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity that is authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives; or
- · in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive,

Provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive. For purposes of this provision, the expression an "offer of securities to the public" in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of us or the underwriters.

## **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive (Qualified Investors) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

#### France

This prospectus has not been prepared in the context of a public offering of financial securities in France within the meaning of Article L.411-1 of the French Code Monétaire et Financier and Title I of Book II of the Reglement Général of the Autorité des marchés financiers (the "AMF") and therefore has not been and will not be filed with the AMF for prior approval or submitted for clearance to the AMF. Consequently, our ordinary shares may not be, directly or indirectly, offered or sold to the public in France and offers and sales of our ordinary shares may only be made in France to qualified investors (investisseurs qualifiés) acting for their own, as defined in and in accordance with Articles L.411-2 and D.411-1 to D.411-4, D.734-1, D.754-1 and D.764-1 of the French Code Monétaire et Financier. Neither this prospectus nor any other offering material may be released, issued or distributed to the public in France or used in connection with any offer for subscription on sale of our ordinary shares to the public in France. The subsequent direct or indirect retransfer of our ordinary shares to the public in France may only be made in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code Monétaire et Financier.

### Notice to Residents of Germany

Each person who is in possession of this prospectus is aware of the fact that no German securities prospectus (wertpapierprospekt) within the meaning of the securities prospectus act (wertpapier-prospektgesetz, the "*act*") of the federal republic of Germany has been or will be published with respect to our ordinary shares. In particular, each underwriter has represented that it has not engaged and has agreed that it will not engage in a public offering in the federal republic of Germany (ôffertliches angebot) within the meaning of the act with respect to any of our ordinary shares otherwise than in accordance with the act and all other applicable legal and regulatory requirements.

#### Notice to Residents of Switzerland

The securities which are the subject of the offering contemplated by this prospectus may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. None of this prospectus or any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

None of this prospectus or any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the securities.

#### Notice to Residents of the Netherlands

The offering of our ordinary shares is not a public offering in The Netherlands. Our ordinary shares may not be offered or sold to individuals or legal entities in The Netherlands unless (i) a prospectus relating to the offer is available to the public, which has been approved by the Dutch Authority for the Financial Markets (Autoriteit Financiële Markten) or by the competent supervisory authority of another state that is a member of the European Union or party to the Agreement on the European Economic Area, as amended or (ii) an exception or exemption applies to the offer pursuant to Article 5:3 of The Netherlands Financial Supervision Act (Wet op het financiel toezicht) or Article 53 paragraph 2 or 3 of the Exemption Regulation of the Financial Supervision Act, for instance due to the offer targeting exclusively "qualified investors" (gekwalificeerde beleggers) within the meaning of Article 1:1 of The Netherlands Financial Supervision Act.

#### Notice to Residents of Japan

The underwriters will not offer or sell any of our ordinary shares directly or indirectly in Japan or to, or for the benefit of, any Japanese person or to others, for re-offering or re-sale directly or indirectly in Japan or to any Japanese person, except in each case pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law of Japan and any other applicable laws and regulations of Japan. For purposes of this paragraph, "*Japanese person*" means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

#### Notice to Residents of Hong Kong

The underwriters and each of their affiliates have not (1) offered or sold, and will not offer or sell, in Hong Kong, by means of any document, any of our ordinary shares other than (a) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance; and (2) issued or had in its possession for the purposes of issue, and will not issue or have in its possession for the purposes of issue, whether in Hong Kong or elsewhere any advertisement, invitation or document relating to our ordinary shares which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to our ordinary shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance and any rules made under that Ordinance. The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

## Notice to Residents of Singapore

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our ordinary shares may not be circulated or distributed, nor may our ordinary shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "Securities and Futures Act"), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Securities and Futures Act or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the Securities and Futures Act.

Where our ordinary shares are subscribed or purchased under Section 275 by a relevant person, which is:

(a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired our ordinary shares under Section 275 except:

(1) to an institutional investor or to a relevant person, or to any person pursuant to an offer that is made on terms that such rights or interest are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets;

- (2) where no consideration is given for the transfer; or
- (3) by operation of law.

## Israel

In the State of Israel, the securities offered hereby may not be offered to any person or entity other than the following:

- Ϋ́ a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;
- Ϋ́ a provident fund as defined in the Control of the Financial Services (Provident Funds) Law 5765-2005, or a management company of such a fund;
- Ÿ an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981;
- Ÿ a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- Y a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;

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- Ÿ an investment advisor or investment distributer, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;
- Ÿ a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- Ÿ an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968, acting on its own account;
- Ÿ a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- Ÿ an entity fully owned by investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- Ÿ an entity, other than an entity formed for the purpose of purchasing securities in this offering, in which the shareholders' equity is in excess of NIS 50 million; and
- <sup>Ÿ</sup> an individual fulfilling the conditions of Section 9 to the supplement to the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account (for this matter, Section 9 to the supplement shall be referred to as "as an investor for the meaning of Section15A(b)(1) of the Securities Law 1968" instead of "as an eligible client for the meaning of this law").

Offerees of the securities offered hereby ("Investors") in the State of Israel shall be required to submit written confirmation that they fall within the scope of one of the above criteria, that they are fully aware of the significance of being an Investor pursuant to such criteria and that they have given their consent (the "Consent"). An appeal to an Investor for the Consent shall not be considered a public offering. This prospectus supplement will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

In addition, if a purchase of securities is made within an institutional trading system, as that term is defined in the Tel Aviv Stock Exchange regulations, a person giving a stock exchange member his prior Consent before submitting a purchase order to the institutional trading system for the first time will be seen as acting within the provisions the above criteria with respect to the Consent, provided that if such person is an investor pursuant to the sixth, tenth, eleventh or twelfth bullet points specified above, such person committed in advance that, until the last business day of the third month in each year, he will renew his Consent, and that if he withdraws his Consent, he will notify the stock exchange member immediately and will cease to give purchase orders in such institutional trading institution.

# EXPENSES

We estimate that the total expenses of this offering payable by us, excluding the underwriting discounts and commissions and expenses, will be approximately \$280,000 as follows:



SEC filing fee	\$ 4,887.96
FINRA filing fee	\$ 6,192.50
Printer fees and expenses	\$ 32,000
Transfer agent fees and expenses	\$ 2,500
Legal fees and expenses	\$ 150,000
Data room and diligence expenses	\$ 10,000
Accounting fees and expenses	\$ 50,000
Miscellaneous	\$ 24,419.54
Total	\$ 280,000

# LEGAL MATTERS

Certain legal matters concerning this offering will be passed upon for us by Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, New York, New York. Certain legal matters with respect to the legality of the issuance of the securities offered by this prospectus will be passed upon for us by Zysman, Aharoni, Gayer & Co., Tel Aviv, Israel. As of the date of this prospectus, certain partners with Zysman Aharoni Gayer & Co. Law Offices beneficially own 401,070 ordinary shares and options to purchase 58,700 of our ordinary shares. Certain legal matters related to the offering will be passed upon for the underwriters by Troutman Sanders LLP, New York, New York and Yigal Arnon & Co., Tel-Aviv, Israel.

## EXPERTS

The financial statements of Alcobra Ltd. for its fiscal years ended December 31, 2012 and December 31, 2011 included herein have been audited by Kost Forer Gabbay & Kasierer (a Member of Ernst & Young Global), independent registered public accounting firm, as set forth in their report thereon. Such financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The address of Kost Forer Gabbay & Kasierer is 3 Aminadav St., Tel-Aviv, Israel 67067.

# ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this registration statement, a substantial majority of whom reside outside of the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and a substantial majority of our directors and officers are located outside of the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have been informed by our legal counsel in Israel, Zysman, Aharoni, Gayer & Co., that it may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum 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 U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

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Subject to specified time limitations and legal procedures, Israeli courts may enforce a United States judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that among other things:

- Ϋ́ the judgment is obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- $\ddot{Y}$  the judgment is final and is not subject to any right of appeal;
- Ÿ the prevailing law of the foreign state in which the judgment was rendered allows for the enforcement of judgments of Israeli courts;
- Ϋ́ adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- <sup>Ÿ</sup> the liabilities under the judgment are enforceable according to the laws of the State of Israel and the judgment and the enforcement of the civil liabilities set forth in the judgment is not contrary to the law or public policy in Israel nor likely to impair the security or sovereignty of Israel;
- Ϋ́ the judgment was not obtained by fraud and does not conflict with any other valid judgments in the same matter between the same parties;
- Ÿ an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- $\ddot{Y}$  the judgment is enforceable according to the law of the foreign state in which the relief was granted.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

# WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at http://www.sec.gov.



We are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements are filing reports with the SEC. Those other reports or other information may be inspected without charge at the locations described above. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information.

We maintain a corporate website at www.alcobra-pharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

# ALCOBRA LTD. (A development stage company)

# FINANCIAL STATEMENTS

# AS OF DECEMBER 31, 2012

# **U.S. DOLLARS IN THOUSANDS**

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

## To Board of Directors and the shareholders of

# ALCOBRA LTD. (A development stage company)

We have audited the accompanying balance sheets of Alcobra Ltd. (a development stage company) ("the Company") as of December 31, 2012 and 2011, and the related statements of comprehensive loss and changes in shareholders' equity (deficiency) and cash flow for each of the two years in the period ended December 31, 2012 and for the period from February 7, 2008 (date of inception) to December 31, 2012. 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 financial position of the Company as of December 31, 2012 and 2011, and the statements of comprehensive loss and cash flows and the changes in shareholders' equity (deficiency) for each of the two years in the period ended December 31, 2012 and for the period from February 7, 2008 (date of inception) to December 31, 2012, in conformity with generally accepted accounting principles in the United States.

Since the date of completion of our audit of the accompanying financial statements and initial issuance of our report thereon dated January 14, 2013, which report contained an explanatory paragraph regarding the Company's ability to continue as a going concern, the Company, as discussed in Note 1(b), has completed an issuance of its Ordinary shares resulting in net proceeds of \$22,000 thousand. Therefore, the conditions that raised substantial doubt about whether the Company will continue as a going concern no longer exist.

Tel-Aviv, Israel January 14, 2013 Except for Note 9(a) and Note 13 to which the date is May 21, 2013 and Note 1(b) to which the date is October 15, 2013

/s/ KOST FORER GABBAY & KASIERER KOST FORER GABBAY & KASIERER

A Member of Ernst & Young Global

# **BALANCE SHEETS**

U.S. dollars in thousands

		December 31,			
	20	2012		2011	
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	97	\$	55	
Short-term bank deposit		-		517	
Receivables and prepaid expenses		83		95	
Total current assets		180		667	
LONG-TERM ASSETS:					
Restricted bank deposits		-		507	
Long-term deposit		3		5	
Property and equipment, net		18		25	
<u>Total</u> long-term assets		21		537	
TOTAL ASSETS	\$	201	\$	1,204	

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

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

		Decem	ber 31,		
	2012			2011	
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)					
LIABILITIES AND SHAREHOLDERS EQUILI (DEFICIENCI)					
CURRENT LIABILITIES:					
Trade payables	\$	23	\$	124	
Other accounts payable		83		95	
Convertible Notes		662		-	
<u>Total</u> current liabilities		768		219	
SHAREHOLDERS' EQUITY (DEFICIENCY):					
Ordinary shares of NIS 0.01 par value -					
10,000,000 shares authorized at December 31, 2012 and 2011; 8,098,581 and 8,096,109 issued shares at					
December 31, 2012 and 2011, respectively; 7,794,256 and 8,096,109 shares outstanding at December 31, 2012					
and 2011, respectively		4		4	
Treasury shares (304,324 Ordinary shares as of December 31, 2012)		*) -		-	
Additional paid- in capital		7,615		7,588	
Deficit accumulated during the development stage		(8,186)		(6,607)	
		()			
<u>Total</u> shareholders' equity (deficiency)		(567)		985	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)	\$	201	\$	1,204	
*) Popresents on amount lower than \$ 1					

\*) Represents an amount lower than \$ 1.

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

# STATEMENTS OF COMPREHENSIVE LOSS

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

	D			F0 20 in	eriod from ebruary 7, 08 (date of ception) to cember 31,
	 Deceml 2012	2011		De	2012
Research and development expenses, net	\$ 818	\$	1,822	\$	3,768
General and administrative expenses	 683		2,084		4,042
Operating loss	1,501		3,906		7,810
Financial expenses, net	78		23		196
Net comprehensive loss	\$ 1,579	\$	3,929	\$	8,006
Deemed dividend			180		180
Net loss attributable to holders of Ordinary shares	\$ 1,579	\$	4,109	\$	8,186
Net basic and diluted loss per share	\$ (0.2)	\$	(0.5)		
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	 7,791,932		7,843,388		

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

# STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands, except share data

	Ordinar	y shares	Preferre	d A shares	Preferred	d 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 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 Net loss	-			-	-	-	28	-	28
INEL IOSS	<u> </u>	-						(666)	(666)
Balance as of December 31, 2008 Issuance of Preferred A shares, net (\$0.92	5,752,600		3 828,867	*) -	-	-	760	(666)	97
per share) Issuance of Preferred A shares granted to	-		- 203,818	*) -	-	-	187	-	187
service provider (\$0.92 per share) Conversion of Preferred A shares into	-		- 190,229	*) -	-	-	175	-	175
Ordinary shares	461,987	*)	- (461,987)	*) -	-	-	-	-	*) -
Net loss			<u> </u>				<u> </u>	(608)	(608)
Balance as of December 31, 2009 Issuance of Preferred B shares and warrants, net (\$2.18 per unit of 1 share	6,214,587		3 760,927	*) -	-	-	1,122	(1,274)	(149)
and 0.25 warrant) Issuance of Preferred B shares and warrants upon conversion of convertible	-			-	342,691	*) -	723	-	723
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 Share based compensation related to	-			-	55,008	*) -	120	-	120
options granted to a service provider and employees	-			-	-	-	242		242
Exercise of options	288,681	*)		-	-	-	*) -	-	*) -
Net loss			<u> </u>					(1,224)	(1,224)
Balance as of December 31, 2010 Conversion of Preferred A and B shares	6,503,268		3 760,927	*) -	526,211	*) -	2,486	(2,498)	(9)
into Ordinary shares Deemed dividend in respect of equity	1,287,138		1 (760,927)	*) -	(526,211)	*) -	(1)	-	-
restructuring Issuance of Ordinary shares upon	-			-	-	-	180	(180)	-
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 Share based compensation related to options granted to consultants and employees	1,379	*)		-	-	-	*) -	-	*) - 1,553
Net loss			<u> </u>				-	(3,929)	(3,929)
Balance as of December 31, 2011 Treasury shares	8,096,109 (304,324)	*)	4 -	-	-	-	7,588	(6,607)	985 *) -
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 -	\$ -		<u>\$ -</u>	\$ 7,615	<u>\$ (8,186</u> )	<u>\$ (567)</u>

\*) Represents an amount lower than \$ 1.

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

# STATEMENTS OF CASH FLOWS

U.S. dollars in thousands, except share data

		Year end December		Period from February 7, 2008 (date of inception) to December 31,
		2012	2011	2012
Cash flows from operating activities				
	<b>^</b>			<b>†</b> (0.000)
Net loss	\$	(1,579) \$	6 (3,929)	\$ (8,006)
Adjustments to reconcile net loss to net cash used in operating activities:		7	C	22
Depreciation		7 12	6	22
Decrease (increase) in receivables and prepaid expenses			(49)	(83)
Increase (decrease) in trade payables		(101)	95	23
Increase (decrease) in other accounts payable Interest on convertible notes		(12) 62	(37)	83 121
			-	
Stock base compensation		26	1,553	2,219
			( )	
Net cash used in operating activities		(1,585)	(2,361)	(5,621)
Cash flows from investing activities				
Purchase of property and equipment		-	(24)	(40)
Investment in (proceeds from) short-term bank deposit		517	(517)	-
Decrease (increase) in long-term deposit		2	-	(3)
Investment in (proceeds from) restricted bank deposit		507	(500)	-
Net cash provided by (used in) investing activities		1,026	(1,041)	(43)
Cash flows from financing activities				
Cash flows from financing activities				
Proceeds from issuance of convertible notes		600		820
Proceeds from loan		-	450	1,200
Issuance of shares, net		1	2,170	3,741
issuance of shares, net		<u> </u>	2,170	5,741
Net cash provided by financing activities		601	2,620	5,761
		001	2,020	
Increase (decrease) in cash and cash equivalents		42	(782)	97
Cash and cash equivalents at the beginning of the period		55	837	-
Cash and cash equivalents at the segmining of the period			007	
Cash and cash equivalents at the end of the period	\$	97 \$	5 55	\$ 97
	\$			J 37
Supplemental disclosure of non-cash investing and financing activities:				
Issuance of Preferred B shares and warrants upon conversion of convertible notes	\$	- \$	2	\$ 224
Issuance of Ordinary shares upon conversion of loans	-	- 4		
issuance of Orumary shares upon conversion of Todas	\$	- 3	5 1,200	\$ 1,200

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

#### U.S. dollars in thousands, except share data

## NOTE 1:- GENERAL

- a. Alcobra Ltd. (the "Company) was incorporated in Israel and commenced its operation on February 7, 2008. The Company is an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug to treat neurological disturbance like Attention Deficit Hyperactivity Disorder ("ADHD"). The Company's objective is to conduct additional clinical trials for its drug called MG01CI (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. The Company has not generated revenue from the sale of any product, and does not expect to generate significant revenue unless and until the obtaining of marketing approval, and commercialize the MG01CI. Accordingly, the Company is considered to be in the development stage as defined in ASC 915, "Development stage entities".
- b. The Company has incurred losses in the amount of \$ 1,579 thousand during the year ended December 31, 2012. The Company has an accumulated deficit in the total amount of \$ 8,186 as of December 31, 2012 and as of that date the accumulated negative cash flow from operating activity is in the amount of \$ 5,621. The Company had its securities listed on the NASDAQ Stock Market (the "NASDAQ") in May 2013, for the purpose of raising capital to finance its operations. The Company completed issuance of its Ordinary shares in a net proceeds of \$22 thousands. Therefore, the conditions that raised substantial doubt about whether the Company will continue as a going concern no longer exists.

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The 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.

#### **SIGNIFICANT ACCOUNTING POLICIES (Cont.) NOTE 2:-**

b. Financial statements in U.S. dollars:

> The Company finances its operation 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 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 nondollar currencies are reflected in the statements of operations as financial income or expenses, as appropriate.

Cash equivalents: c.

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

d. 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, 2011, the Company's bank deposits were in U.S. dollars and bore interest at a weighted average interest rate of 1.85%.

Restricted bank deposits: e.

> Restricted bank deposits are pledged in favor of the bank which provides to the Company guarantees with respect to office lease agreements and credit card usage.

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

# U.S. dollars in thousands, except share data

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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 2012 and 2011, no impairment losses have been identified.

g. Long-term deposits:

Long-term deposits include long-term deposits for motor vehicles under operating leases, presented at their cost.

h. Research and development expenses:

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

i. Severance pay:

The Company's liability for severance pay is pursuant to Section 14 of the Severance Compensation Act, 1963 ("Section 14"), all the 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 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.

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

# NOTES TO FINANCIAL STATEMENTS U.S. dollars in thousands, except share data

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Income taxes:

The Company account for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, 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, 2012 and 2011 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, short term bank deposit and restricted bank deposits.

Cash and cash equivalents, short term bank deposit and restricted bank deposits are invested in major banks in Israel. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments.

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

l. Fair value of financial instruments:

ASC 820, "Fair Value Measurements and Disclosures", defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

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

As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1 Valuations based on quoted prices in active markets for identical assets that the Company has the ability to access. Valuation adjustments and block discounts are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.
- Level 2 Valuations based on one or more quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The carrying amounts of cash and cash equivalents, short-term bank deposits, restricted bank deposits, accounts payable, and other 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."

All outstanding stock options and warrants have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented.

# NOTES TO FINANCIAL STATEMENTS U.S. dollars in thousands, except share data

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

n. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation" that requires the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to employees, 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 statement of operations.

The Company selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the fair value method for of its stockoptions 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 is not traded on any stock exchange market, quoted prices of the Company's share are unavailable. According to ASC 718, due to insufficient or no historical data for a 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.

*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 to 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.

# U.S. dollars in thousands, except share data

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Because there has been no public market for the Company's Ordinary shares, the fair value of the Ordinary shares underlying the options through December 31, 2012, had been determined by the Company's management, using the assistance of an independent valuation firm. The valuation of the Ordinary shares was based on recent third-party transactions in the equity of the Company by applying the option-pricing method.

# NOTE 3:- RECEIVABLES AND PREPAID EXPENSES

		December 31,			
	201	2		2011	
Government authorities	\$	10	\$	93	
Prepaid expenses		66		2	
Advance to suppliers		7		-	
	<u>\$</u>	83	\$	95	

# NOTE 4: PROPERTY AND EQUIPMENT, NET

11
19
7
14
40
9
*) -
6
15
25

\*) Represents an amount lower than \$ 1.

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

# U.S. dollars in thousands, except share data

# NOTE 5:- OTHER ACCOUNTS PAYABLE

	December 31,			
20	2012		2011	
\$	31	\$	35	
	52		60	
\$	83	\$	95	
	\$\$	\$ 31 52	\$ 31 \$ 52	

#### NOTE 6:- CONVERTIBLE NOTES

- a. On June 23, 2009, the Company entered into a convertible note agreement. Total loan consideration amounted to \$220. The loan bore interest of 4% per annum. The conversion price was set to be at 20% discount of such shares of the following financing round. In case the total convertible note amount remains due and outstanding upon the elapse of 12 months from closing, then the total convertible note amount shall be automatically converted into an amount of shares of the Company reflecting a pre-money Company valuation of \$ 7,169 on fully diluted basis. In February 2010, as part of a financing round (see also Note 9(c)(6)) the convertible note and the accumulated interest, in an amount of \$ 224 were converted into 128,512 Preferred B2 shares.
- b. During 2012, the Company issued convertible promissory notes to certain investors for a total amount of \$ 600. The convertible notes bear an annual interest rate of 6%. According to the terms of the convertible notes, the total amount shall be automatically converted into securities of the Company upon the earlier of the following events: (i) a financing round, or (ii) Initial Public Offering ("IPO"), at a 25% discount paid for such shares in the course of a financing round or the price per share as determined for such shares in an IPO, as applicable. In case the total convertible notes amount remains due and outstanding upon the elapse of 12 months from closing, then the total convertible notes amount shall be automatically converted into an amount of Ordinary shares of the Company reflecting a premoney Company valuation of \$ 25,000 on fully diluted basis.

The convertible notes have a conversion option related to financing round and/or IPO that continuously resets as the underlying share price increases or decreases to provide a fixed value of shares. The conversion upon financing round and/or IPO was determined to be the predominant event and therefore the entire instrument was considered to be a liability pursuant to ASC No. 480 "Distinguishing Liabilities from Equity". The convertible notes are presented at their redemption amount, which includes the principal amount of the convertible notes, the accumulated interest and additional redemption amount accrued over the term of the convertible notes, using the interest method, which approximates the fair value.

Upon conversion of the convertible note in February 2010, the entire redemption amount was derecognized against additional paid in capital in the amount of \$ 279. As of December 31, 2012, the convertible notes redemption amount was \$ 662.

# U.S. dollars in thousands, except share data

# NOTE 7:- INCOME TAXES

a. Tax rates applicable to the Company:

The Company is incorporated in Israel. Taxable income of Israeli companies is subject to tax at the rate of 24% in 2011 and 25% in 2012 and onwards.

b. Net operating losses carry forward:

The Company has accumulated losses for tax purposes as of December 31, 2012 in the amount of approximately \$ 4,600 which may be carried forward and offset against taxable income in the future for an indefinite period.

c. 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,			
		2012		2011	
Operating loss carry forward	\$	1,153	\$	703	
Reserves and allowances	-	308	_	341	
		4 464		1.0.11	
Net deferred tax asset before valuation allowance		1,461		1,044	
Valuation allowance		(1,461)		(1,044)	
Net deferred tax asset	\$	_	\$	-	

As of December 31, 2012, the Company has provided valuation allowances of \$ 1,461 in respect of deferred tax assets resulting from tax loss carry forward and other temporary differences. 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.

- d. No liability for uncertain tax positions was recorded as a result of implementation of ASC 740.
- e. The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowances in respect of deferred taxes relating to accumulated net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

## U.S. dollars in thousands, except share data

# NOTE 8:- CONTINGENT LIABILITIES AND COMMITMENTS

- a. The Company is engaged in an operating lease agreement for its office facilities. Future minimum non cancelable rental payments under the operating lease are \$4. The rent expenses for the years ended December 31, 2012 and 2011 amounted to \$44 and \$61, respectively.
- b. The Company has entered into an operating lease agreement for its vehicles until December 2013. The rent expenses for the years ended December 31, 2012 and 2011 amounted to \$18 and \$29, respectively. Future minimum payments under the lease are as follows:

Year ended December 31,	 Total
2013	\$ 14
2014	 3
	\$ 17

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, 2012. 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 \$ 112 as of December 31, 2012. 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:

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).

# U.S. dollars in thousands, except share data

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

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. On February 7, 2008, (inception day) the Company issued 5,752,600 Ordinary shares in consideration of their par value.
  - 2. In February 2008, the Company entered into an investment agreement, according to the agreement, the Company issued 434,814 Preferred A shares in consideration of \$ 400.
  - 3. In May 2008, an agreement to purchase Preferred A shares was signed with a new investor (the "Investor"). Accordingly, as of December 31, 2008, 95,117 Preferred A shares were issued in consideration of \$ 88. In January 2009, additional 95,112 Preferred A shares, were issued in consideration of \$ 87.

In addition, the Company and the Investor agreed that the Investor shall supply clinical trial services in a value of up to \$250 in exchange of up to 271,757 Preferred A shares. As of December 31, 2008, the investor provided part of the clinical trial services, for which 81,528 Preferred A shares were issued.

In January 2009, the Investor carried out the rest of the services and an additional 190,229 Preferred A shares were issued.

- 4. In July 2008, the Company entered into an investment agreement. Accordingly, as of December 31, 2008, 217,408 Preferred A shares were issued in consideration of \$ 184. In February 2009, 108,706 Preferred A shares were issued in consideration of \$ 100.
- 5. In relation with the convertible loan agreement dated June 2009, in July 2009, 461,987 Preferred A shares of an existing investor that did not participate in the loan agreement, were converted into 461,987 Ordinary shares.
- 6. In February 2010, an agreement to purchase Preferred B shares was signed. Accordingly, 183,356 Preferred B shares were issued in consideration of \$ 400. In addition, the Convertible Notes were converted (see Note 6(a)). As a part of the above agreement, the Company granted to investors warrants to purchase 77,965 Preferred B-3 shares at an exercise price of \$ 2.73 per share. The warrants will expire five years after the date of grant. As of December 31, 2012, the warrants were not exercised.

# U.S. dollars in thousands, except share data

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

As a part of the 2010 Agreement, the Company entered into a service agreement according to which a service provider will provide clinical trial services for up to 55,008 Preferred B-1 shares. As of December 31, 2010, the services provider supplied the clinical trial services and 55,008 Preferred B-1 shares and 11,458 warrants to Preferred B-3 were issued. The Company recorded a compensation expense in the amount of \$120 in the year ended December 31, 2010.

In August 2010, additional 159,335 preferred B shares and 39,834 warrants to preferred B-3 were issued for a total consideration of \$323 (net of \$26 issuance expenses).

7. On November 17, 2010, the Company entered into an agreement with a strategic investor (the "Strategic Investor") under which, the Company received a loan in an amount of \$ 750, which was extended in February 2011, for an additional amount of \$ 450. The loan was to be repaid in February 2011, if the parties do not reach a Buyout agreement. To the extent a Buyout agreement is executed by March 2011, the loan will be converted into Ordinary shares. In March 2011, the Buyout agreement was executed and the Company issued to the Strategic Investor 199,979 Ordinary shares in consideration of \$ 2,170 (net of \$130 issuance expenses).

Additionally, 104,345 Ordinary shares were issued in consideration of the loan amount. According to the Buyout agreement, the Strategic Investor has certain options to buy shares from the Company's shareholders according to certain milestones and shall hold 100% of the Company's shares. According to the Buyout agreement, if one of the options is not exercised, within the agreed time, the Buyout agreement is terminated and the shares issued will be transferred to the Company free of charge. Due to the fact that the Strategic Investor did not exercise his option, in January 2012, the agreement was terminated, and the Strategic Investor transferred 304,324 Ordinary shares to back the Company, without any consideration.

Prior to the closing of the Buyout agreement and as a condition to it, the Company affected an equity restructuring, under which, all of the Company's Preferred shares (1,287,138 Preferred shares) were converted into Ordinary shares at 1:1 ratio. In addition, all options, warrants that were convertible into share capital of the Company other than Ordinary shares were replaced or exchanged at 1:1 ratio to notes and rights entitling their holders the right to purchase or receive Ordinary shares. In accordance with ASC 718-20-35-6, the Company recorded a compensation expense in the amount of \$ 15 and of \$ 1,466 in the years ended December 31, 2012 and 2011, respectively. Additionally, a deemed dividend to other Ordinary shareholders was recorded in the amount of \$ 180 for the year ended December 31, 2011.

# U.S. dollars in thousands, except share data

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

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 1,063,984 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, 2012, 7,009 options were still available for future grants under the Plan.

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

	Year ended December 31,					
	2012			2011		
	Number of options		Weighted average exercise price	Number of options		Weighted average exercise price
Outstanding at beginning of year	465,520	\$	0.21	544,472	\$	0.18
Granted	-		-	-		-
Exercised	(2,471)	\$	0.33	(1,379)	\$	0.33
Forfeited	(1,931	\$	0.33	(77,572)	\$	0.01
Outstanding at end of year	461,118	\$	0.2	465,520	\$	0.21
Vested and expected to vest	461,118	\$	0.2	465,520	\$	0.21
		_				
Options exercisable at the end of the period	366,464	\$	0.22	305,017	\$	0.2

As of December 31, 2012, the weighted-average remaining contractual term of the outstanding and exercisable options is 7.098 years; the aggregated intrinsic value of outstanding options and exercisable options is \$38 and \$38, respectively. As of December 31, 2012, the unrecognized compensation cost is \$11 and \$1 to be recognized in 2013 and 2014, respectively.

In addition, the Company granted an employee the following: (a) Options to purchase 88,050 Ordinary shares granted in 2010, at an exercise price of \$ 0.33 per share. The options will vest immediately prior to and subject to the event of a merger of the Company into another corporation; (b) Options to purchase 89,553 Ordinary shares granted in December 2012. The options will vest immediately prior to and subject to the earlier of: (i) the next round of equity financing of at list \$5,000; (ii) the consummation of a merger, acquisition or sale of the securities of the Company; or (iii) the event of an Initial Public Offering of the Company's Ordinary shares (a "Transaction").

According to ASC-718-10-20, compensation cost will be recognized if the performance condition is satisfied. As of December 31, 2012, no compensation cost was recognized.

#### U.S. dollars in thousands, except share data

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

In addition, in December 2012, the Company granted a director the following options: (a) Options to purchase 89,553 Ordinary shares. The exercise price shall be the effective price determined in the course of the Transaction; (b) Options to purchase 22,388 Ordinary shares according to the 2010 Plan. The exercise price shall be the effective price determined in the course of the Transaction. The options will vest subject and upon initiation of phase III clinical studies. According to ASC-718-10-20, compensation cost will be recognized if the performance condition is satisfied.

According to ASC-718-10-55-83, grant date did not occur because the recipient did not begin to benefit from or be adversely affected by the changes in the price of the shares of the Company. As of December 31, 2012, no compensation cost was recognized.

#### e. Options granted to consultants:

The Company granted options to certain service providers and accounted for these options in accordance with ASC 505-50.

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.

#### f. 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 o Decem	 -	Fo 20 in	eriod from ebruary 7, 08 (date of ception) to cember <u>31,</u>
	 2012	 2011		2012
Research and development, net	\$ *) -	\$ 18	\$	483
General and administrative expenses	26	1,535		1,736
	\$ 26	\$ 1,553	\$	2,219

\*) Represents an amount lower than \$ 1.



#### U.S. dollars in thousands, except share data

#### NOTE 10:- RELATED PARTY BALANCES AND TRANSACTIONS

Balances with related parties:

		December 31,
	20	012 2011
Convertible Notes (e)	<u>\$</u>	610 \$ -
Other accounts payable (c)	\$	21 \$ 19

Related parties' expenses:

		Year ended December 31,			
		2012 2			
Amounts charged to: *)					
General and administrative expense (a) (b) (c) (d)	<u>\$</u>	401	\$	1,786	
Financial expense (e)	\$	60	\$	-	

\*) Including share based compensation expenses for the years ended December 31, 2012 and 2011 in the amounts of \$ 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 directors, as a contractor to render management, finance and operation services. The Company pays the consultant an amount of \$ 7 per month.
- 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.
- 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.
- 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 is entitled to a gross monthly salary of \$ 14. Besides a base salary, the CEO 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 a leased car and cellular telephone.
- e. One of the Company's shareholders invested as part of the Company's issuance of the Convertible Notes with terms as described in Note 6(b).

#### NOTES TO FINANCIAL STATEMENTS

#### U.S. dollars in thousands, except share data

#### NOTE 11:- FINANCIAL EXPENSES, NET

	Year ( Decem			Fel 200 inco	iod from oruary 7, 8 (date of eption) to ember 31,
	2012		2011		2012
Financial expenses:					
Interest expense	\$ 13	\$	3	\$	23
Exchange rate	15		41		92
Interest on convertible notes	52		-		107
		_			
	80		44		222
Financial income:	 				
Interest income	2		21		26
	 	_			
	2		21		26
	\$ 78	\$	23	\$	196

### NOTE 12:- BASIC AND DILUTED NET LOSS PER SHARE

The following table sets forth the computation of the Company's basic and diluted net loss per share of Ordinary share:

	Year ended December 31				
	2012			2011	
Net loss attributable to Ordinary shares as reported	\$	(1,579)	\$	(4,109)	
Shares used in computing net loss per share of Ordinary shares, basic and diluted		7,791,932		7,843,388	
Net loss per share of Ordinary share, basic and diluted	\$	(0.2)	\$	(0.5)	

For the years ended December 31, 2012 and 2011, all outstanding options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

#### NOTE 13:- SUBSEQUENT EVENTS

a. During March 2013, the Company's shareholders resolved to amend the vesting term of 88,050 options granted to an employee in 2010, such that the options will also vest immediately prior to and subject to the completion of an initial public offering of the Company's Ordinary shares. See also Note 9.

#### U.S. dollars in thousands, except share data

#### NOTE 13:- SUBSEQUENT EVENTS (Cont.)

- b. During February 2013, the Company issued convertible promissory notes to certain investors for a total amount of \$ 115. The terms of the convertible promissory notes issued in 2012. For the terms see Note 6 (b).
- c. During March 2013, the Company increased the monthly fee for its consultant who is also one of the Company's shareholders and directors to an amount of \$ 12 (see also Note 10 (a)), and the monthly fee for its contractor who is also one of the Company's shareholders to an amount of \$ 5 (see also Note 10 (c)). These amendments are subject to and effective upon consummation of initial public offering.
- d. During March 2013, the Company's general meeting resolved to increase the Company's authorized shares to 50,000,000 Ordinary shares.
- e. The Company received a short term loan from a bank in the amount of \$69. The loan bears an annual interest rate of 4.8% paid on a weekly basis and will be settled no later than July 2, 2013.

#### ALCOBRA LTD. (A development stage company)

#### INTERIM FINANCIAL STATEMENTS

#### AS OF JUNE 30, 2013

#### **U.S. DOLLARS IN THOUSANDS**

#### UNAUDITED

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#### **BALANCE SHEETS**

U.S. dollars in thousands

Short-term deposit     4,000       Receivables and prepaid expenses     87       Total current assets     21,680       LONG-TERM ASSETS:       Long-term deposit     7		 une 30, 2013 naudited	ember 31, 2012
Cash and cash equivalents\$ 17,593\$ 95Short-term deposit4,000Receivables and prepaid expenses8788Total current assets21,68018LONG-TERM ASSETS:7	ASSETS		
Short-term deposit       4,000         Receivables and prepaid expenses       87       8         Total current assets       21,680       18         LONG-TERM ASSETS:       7       18			
Receivables and prepaid expenses     87     8       Total current assets     21,680     18       LONG-TERM ASSETS:     7		\$	\$ 97
Total current assets     21,680     18       LONG-TERM ASSETS:     7			-
LONG-TERM ASSETS: Long-term deposit 7	Receivables and prepare expenses	 87	 83
Long-term deposit 7	<u>Total</u> current assets	 21,680	 180
	LONG-TERM ASSETS:		
Property and equipment, net 17		7	3
	Property and equipment, net	 17	 18
Total long-term assets 24	<u>Total</u> long-term assets	 24	 21
<b>TOTAL ASSETS</b> \$ 21,704         \$ 20	TOTAL ASSETS	\$ 21,704	\$ 201

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

**BALANCE SHEETS** 

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

	June 30, 2013 Unaudited		D	ecember 31, 2012
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)				
CURRENT LIABILITIES:				
Trade payables	\$	67	\$	23
Other accounts payable		276		83
Convertible Notes		-		662
Total current liabilities		343		768
SHAREHOLDERS' EQUITY (DEFICIENCY):				
Ordinary shares of NIS 0.01 par value - 50,000,000 and 10,000,000 shares authorized at June 30, 2013 and December 31, 2012, respectively; 11,432,325 and 8,098,580 shares issued shares at June 30, 2013				
(unaudited) and December 31, 2012, respectively; 11,128,001 and 7,794,256 shares outstanding at				
June 30, 2013 (unaudited) and December 31, 2012, respectively		32		4
Treasury shares (304,324 Ordinary shares as of December 31, 2012 and June 30, 2013)		*) -		*) -
Additional paid- in capital		31,231		7,615
Deficit accumulated during the development stage		(9,902)		(8,186)
<u>Total</u> shareholders' equity (deficiency)		21,361		(567)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	21,704	\$	201
*) Represents an amount lower than \$ 1.				

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

## STATEMENTS OF COMPREHENSIVE LOSS

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

	Six months ended June 30,			Period from February 7, 2008 (date of inception) to June 30, 2013		
		2013		2012		
		Unau	dited	,		
Research and development expenses, net	\$	396	\$	632	\$	4,164
General and administrative expenses		1,114		356		5,156
Operating loss		1,510		988		9,320
Financial expenses, net		206		13		402
Net comprehensive loss	\$	1,716	\$	1,001	\$	9,722
Deemed dividend		-		-	\$	180
Net loss attributable to holders of Ordinary shares	\$	1,716	\$	1,001	\$	9,902
Net basic and diluted loss per share	\$	(0.20)	\$	(0.13)		-
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share		8,397,070		7,791,785		_

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

#### STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands, except share data

-	Ordinar Number	y shares Amount	Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficiency)
-					(constant)
Balance as of December 31, 2011	8,096,109		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		le l			
employees	-	-	26	-	26
Net loss	-	-	-	(1,579)	(1,579)
Balance as of December 31, 2012	7,794,256	4	7,615	(8,186)	(567)
Share based compensation related to options granted to consultants and					
employees	-	-	744	-	744
Issuance of shares upon exercise of cashless warrants	85,192	*) -	-	-	*) -
Issuance of Ordinary 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
Net loss			-	(1,716)	(1,716)
Balance as of June 30, 2013 (unaudited)	11,128,001	\$ 32	\$ 31,231	\$ (9,902)	\$ 21,361

\*) Represents an amount lower than \$ 1.

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

STATEMENTS OF CASH FLOWS U.S. dollars in thousands, except share data

	Six montl June			F 20 in	eriod from ebruary 7, 08 (date of ception) to June 30, 2013
	 2013	2012			
		Unaudit	ed		
Cash flows from operating activities					
Net loss	\$ (1,716)	\$ (	1,001)	\$	(9,722)
Adjustments to reconcile net loss to net cash used in operating activities:	2				0.5
Depreciation	3		4		25
Gain from sale of property and equipment	1		-		1
Decrease (Increase) in receivables and prepaid expenses	(4)		56		(87)
Increase (decrease) in trade payables	44		(102)		67
Increase in other accounts payable	193		41		276
Interest on convertible notes	203		-		324
Stock base compensation	 744	<u>.</u>	16		2,963
Net cash used in operating activities	(532)		(986)		(6,153)
	 (00_)	<u> </u>	(000)		(0,100)
Cash flows from investing activities					
Purchase of property and equipment	(3)		-		(43)
Decrease (increase) in long-term deposit	(4)		2		(7)
Proceeds from (investment in) short-term bank deposit	(4,000)		465		(4,000)
Proceeds from restricted bank deposit	-		507		-
Net cash provided by (used in) investing activities	 (4,007)		974		(4,050)

# STATEMENTS OF CASH FLOWS U.S. dollars in thousands, except share data

Cash flows from financing activities						
Proceeds from loan		-		-		1,200
Proceeds from issuance of convertible notes		115		-		935
Issuance of shares, net		21,920		-		25,661
Net cash provided by financing activities		22,035		-		27,796
	_	<u> </u>				
Increase (decrease) in cash and cash equivalents		17,496		(12)		17,593
Cash and cash equivalents at the beginning of the period		97		55		-
		<u> </u>				
Cash and cash equivalents at the end of the period	\$	17,593	\$	43	\$	17,593
			-		<u> </u>	
Supplemental disclosure of non-cash investing and financing activities:						
Supplemental disclosure of non-cush investing and inducing activities.						
Issuance of Preferred B shares and warrants upon conversion of convertible notes		_		_	\$	224
	¢	000	_		φ	
Issuance of Ordinary shares upon conversion of loans	3	980		-	\$	2,180

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

#### U.S. dollars in thousands, except share data

#### NOTE 1:- GENERAL

- a. Alcobra Ltd. (the "Company) was incorporated in Israel and commenced its operation on February 7, 2008. The Company is an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug to treat neurological disturbance like Attention Deficit Hyperactivity Disorder ("ADHD"). The Company's objective is to conduct additional clinical trials for its drug called MG01CI (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. The Company has not generated revenue from the sale of any product, and does not expect to generate significant revenue unless and until the obtaining of marketing approval, and commercialize the MG01CI. Accordingly, the Company is considered to be in the development stage as defined in ASC 915, "Development stage entities".
- b. The Company is in the development stage. As reflected in the accompanying unaudited interim financial statements, the Company incurred a loss for the six month period ended June 30, 2013 of \$1,716 and had a negative cash flow from operating activities of \$532 during the six month period ended June 30, 2013. The accumulated deficit as of June 30, 2013 is \$9,902. The Company has not yet generated revenues from product sale.
- c. During May 2013, the Company completed an Initial Public Offering (the "IPO") in the "NASDAQ" and issued 3,125,000 ordinary shares in consideration of approximately \$22,000, net.

#### NOTE 2:- UNAUDITED INTERIM FINANCIAL STATEMENTS

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. The Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the 2012 annual financial statements and the notes thereto.

Operating results for the six months period ended June 30, 2013, are not necessarily indicative of the results that may be expected for the year ended December 31, 2013.

#### U.S. dollars in thousands, except share data

#### NOTE 3:- SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies applied in the annual financial statements of the Company as of December 31, 2012 are applied consistently in these financial statements. For further information, refer to the financial statements as of December 31, 2012.

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 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 4:- CONVERTIBLE NOTES

- a. During 2012, the Company issued convertible promissory notes to certain investors for a total amount of \$ 600. The convertible notes bore an annual interest rate of 6%. According to the terms of the convertible notes, the total amount shall be automatically converted into securities of the Company upon the earlier of the following events: (i) a financing round, or (ii) Initial Public Offering ("IPO"), at a 25% discount paid for such shares in the course of a financing round or the price per share as determined for such shares in an IPO, as applicable. In case the total convertible notes amount remains due and outstanding upon the elapse of 12 months from closing, then the total convertible notes amount shall be automatically converted into an amount of Ordinary shares of the Company reflecting a premoney Company valuation of \$ 25,000 on fully diluted basis.
- b. During February and March 2013, the Company issued convertible promissory notes to certain investors for a total amount of \$ 115. The terms of the convertible promissory notes are the same as the terms of the convertible promissory notes issued in 2012.

The convertible notes had a conversion option related to financing round and/or IPO that continuously resets as the underlying share price increases or decreases to provide a fixed value of shares. The conversion upon financing round and/or IPO was determined to be the predominant event and therefore the entire instrument was considered to be a liability pursuant to ASC No. 480 "Distinguishing Liabilities from Equity". The convertible notes were presented at their redemption amount, which included the principal amount of the convertible notes, the accumulated interest and additional redemption amount accrued over the term of the convertible notes, using the interest method, which approximated the fair value.

In connection with the 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 Six months ended June 30, 2013 amounted to \$203.

#### U.S. dollars in thousands, except share data

#### NOTE 5:- CONTINGENT LIABILITIES AND COMMITMENTS

- a. The Company is engaged in an operating lease agreement for its office facilities. Future minimum non cancelable rental payments under the operating lease are \$4. The rent expenses for the Six month ended June 30, 2013 amounted to \$16.
- b. On June 2013 the Company entered into an operating lease agreement for its vehicles until 2016. Future minimum non cancelable rental payments under the operating lease are \$11. The rent expenses for the Six month ended June 30, 2013 amounted to \$9.
- 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 June 30, 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 \$113 as of June 30, 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 6:- SHAREHOLDERS' EQUITY (DEFICIENCY)

a. General:

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 4.87-to-one bonus shares (equivalent to a 5.87-for-1 stock split) that was effective immediately prior to the effectiveness of the registration statement in May 2013.

During March 2013, the Company's general meeting resolved to increase the Company's authorized shares 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.

#### U.S. dollars in thousands, except share data

#### NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

c. Issuances of share:

During May, 2013, the Company completed an Initial Public Offering (the "IPO") in the "NASDAQ" and issued 3,125,000 ordinary shares in consideration of approximately \$22,000, net.

Following the IPO and according to the terms of the convertible notes (see also Note 4), the notes were automatically converted into 123,552 ordinary shares of the Company. In addition, 120,255 warrants were exercised into 85,189 ordinary shares of the Company, using the cashless exercise method.

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 1,063,984 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 June 30, 2013, 7,009 options were still available for future grants under the Plan. (See also Note 9(b)).

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

	Six months ended June 30, 2013			
	Number of options	Weighted average exercise price		
Outstanding at beginning of period	461,118	\$	0.20	
Granted *)	289,544	\$	5.67	
Outstanding at end of period	750,662	\$	2.31	
Vested and expected to vest	750,662	\$	2.31	
Options exercisable at the end of the period	486,063	\$	0.12	

The weighted average grant date fair value of options granted during the period ended June 30, 2013 was \$5.8. As of June 30, 2013, the weighted-average remaining contractual term of the outstanding and exercisable options is 6.6 years; the aggregated intrinsic value of outstanding options and exercisable options is \$3,285. As of June 30, 2013, the unrecognized compensation cost is \$ 303 and \$310 to be recognized in 2013 and 2014, respectively.

#### U.S. dollars in thousands, except share data

#### NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

\*) Including 22,388 options to purchase Ordinary shares according to the 2010 Plan granted in May 2013 to a director. The exercise price is \$8. The vesting of the options is subject to certain performance conditions.

#### e. Options granted to consultants:

The Company granted options to certain service providers and accounted for these options in accordance with ASC 505-50.

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.

f. Warrants granted to underwriters:

The outstanding options granted to the Company's underwriters 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		

#### U.S. dollars in thousands, except share data

#### NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

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:

	Six month June		Period from February 7, 2008 (date of inception) to June 30, 2013
	2013	2012	
		Unaudited	
Research and development, net	177	*) -	661
General and administrative expenses	567	16	2,303
	744	16	2,964

#### \*) Represents an amount lower than \$ 1.

#### NOTE 7:- RELATED PARTY BALANCES AND TRANSACTIONS

Balances with related parties:

		ne 30, 013	Dec	ember 31, 2012
	Una	udited		
Convertible Notes (e)			\$	610
Other accounts payable (c) (d)	\$	40	\$	42

Related parties' expenses:

		Six months ended June 30,			
	2013	2012			
	Unau	dited			
Amounts charged to: *)					
General and administrative expense (a) (b) (c) (d)	774	178			
Research and development expenses (d)	224	26			
	<u>\$ 998</u>	\$ 204			

\*) Including share based compensation expenses for the Six-months ended June 30, 2013 and for the year ended December 31, 2012 in the amounts of \$711 and \$26, respectively.

#### U.S. dollars in thousands, except share data

#### NOTE 7:- RELATED PARTY BALANCES AND TRANSACTIONS (Cont.)

- a. On March 1, 2008, the Company signed an agreement with a consultant, who is also one of the Company's shareholders and directors, as a contractor to render management, finance and operation services. The Company pays the consultant an amount of \$ 7 per month. During March 2013, the Company increased the monthly fee for its consultant to an amount of \$ 12. The amendment was effective upon consummation of the initial public offering on May 2013. Subsequent to the financial statements' date and in connection to the consummation of the IPO, the Company granted the consultant a bonus in the amount of \$50.
- 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.
- 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 March 2013, the Company increased the monthly fee for its contractor to an amount of \$5. The amendment was effective upon consummation of the initial public offering in May 2013.
- 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 is entitled to a gross monthly salary of \$ 14. Besides a base salary, the CEO 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 a leased car and CEO telephone. During January 2013, the Company increased the monthly fee for its contractor to an amount of \$ 15 which became effective upon the Company's IPO. On June 30, 2013, the Company granted the CEO a bonus in the amount of \$75 in connection with the consummation of the IPO . In addition, subsequent to the financial statements' date the Company increased the bonus amount in \$125, to a total of \$200.
- e. Two of the Company's shareholders invested as part of the Company's issuance of the Convertible Notes with terms as described in Note 4.

#### U.S. dollars in thousands, except share data

#### NOTE 8:- BASIC AND DILUTED NET LOSS PER SHARE

The following table sets forth the computation of the Company's basic and diluted net loss per share of Ordinary share:

	Six months ended June 30			
	2013 2012			2012
Net loss attributable to Ordinary shares as reported	\$	(1,716)	\$	(4,109)
Shares used in computing net loss per share of Ordinary shares, basic and diluted		8,397,070		7,791,785
Net loss per share of Ordinary share, basic and diluted	\$	(0.2)	\$	(0.13)

For the six months ended June 30, 2013, all outstanding options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

#### NOTE 9:- FINANCIAL EXPENSES, NET

	Six months ended June 30,			Period from February 7, 2008 (date of inception) to June 30,		
	2013		2012		2013	
Financial expenses:						
Interest expense	\$ 2	\$	1	\$	25	
Exchange rate	1		15		93	
Convertible notes expenses	 203				310	
	206		16		428	
Financial income:	 					
Interest income	 -		3		26	
	-		3		26	
	\$ 206	\$	13	\$	402	

#### U.S. dollars in thousands, except share data

#### NOTE 10:- SUBSEQUENT EVENTS

- a. During July 2013, the Company's board of directors resolved to form a wholly-owned subsidiary in the State of Delaware (the "Subsidiary"), to be named Alcobra Inc.
- b. During August 2013, the Company's board of directors resolved to increase the number of options available for grant under the option plan by 105,062 to a total of 112,071 options available.
- c. During August 2013, the Company's board of directors resolved to grant employees 56,431 options to purchase Ordinary shares, at an exercise price of \$8 per share. The vesting schedule shall be according to the 2010 option plan. In addition, the Company's board of directors resolved to grant directors 24,000 options to purchase Ordinary shares, at an exercise price of \$12.99 per share. The vesting schedule shall be three year period.

In addition, the Company granted an employee the following options: (i) 55,640 options to purchase Ordinary shares at an exercise price of \$14.61 per share. The vesting schedule shall be according to the 2010 options plan; and (ii) options to purchase 0.75% of the Company's issued and outstanding Ordinary shares upon the performance of certain clinical trials. The options shall be granted in three trenches of 0.25% each. The options will vest ratably on a monthly basis over 3 years. ASC 718 requires the Company to recognize compensation cost relating to share-based payment commencing on the service inception date, and over the requisite service period, which is the period of time over which an employee must provide service in exchange for an award under a share-based payment arrangement.



## 2,000,000 Ordinary Shares

PROSPECTUS

October 24, 2013

Stifel

**Aegis Capital Corp** 

**JMP Securities**