Galmed Pharmaceuticals Ltd.
Form 424B4
March 13, 2014

Filed pursuant to Rule 424(b)(4)
Registration No. 333-193792
Registration No. 333-194526

2,837,400 ORDINARY SHARES

GALMED PHARMACEUTICALS LTD.

Galmed Pharmaceuticals Ltd. is offering its ordinary shares, NIS 0.01 par value, or the Shares, in a firm commitment underwritten initial public offering. Prior to this offering, there has been no public market for our ordinary shares. The initial public offering price is $13.50 per Share.

The Shares have been approved for listing on the Nasdaq Capital Market under the symbol GLMD.

	Per Share	Total
Initial public offering price	$13.50	$38,304,900
Underwriting discounts and commissions[(1)]	$0.945	$2,681,343
Proceeds to us (before expenses)	$12.555	$35,623,557

(1) The underwriters will receive compensation in addition to the underwriting discounts and commissions. See Underwriting for a description of compensation payable to the underwriters.

We have granted a 45 day option to the underwriters to purchase up to an additional 425,610 Shares solely to cover over-allotments, if any.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 and, as such, may elect to comply with certain reduced public company reporting requirements.

Investing in our ordinary shares involves a high degree of risk. See Risk Factors beginning on page 11 of this prospectus for a discussion of information that should be carefully considered in connection with an investment in our ordinary shares.

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.

The underwriters expect to deliver the Shares to purchasers in the offering on or about March 18, 2014.

Sole Book-Running Manager

Maxim Group LLC

Co-Managers

MLV & Co.

Feltl and Company

Prospectus dated March 12, 2014.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in, or incorporated by reference in, this prospectus and any free writing prospectus prepared by, or on behalf of, us or to which we have referred you to or otherwise authorized. Neither we nor any of the underwriters have 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 hereof, regardless of the time of delivery of this prospectus or any sale of the Shares. Our business, financial condition, results of operations and prospectus may have changed since that date. Neither we nor the underwriters take any responsibility for, and can provide no assurance as to the reliability of, any information other than the information in this prospectus and any free writing prospectus prepared by us or on our behalf. Neither the delivery of this prospectus nor the sale of our ordinary shares means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy these ordinary shares in any circumstances under which such offer or solicitation is unlawful.

Before you invest in the Shares, you should read the registration statement (including the exhibits thereto and documents incorporated by reference therein) of which this prospectus forms a part.

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 observe any restrictions relating to this offering and the distribution of this prospectus.

Our reporting currency and functional currency is the U.S. dollar or $. All amounts in this prospectus are in U.S. dollars, unless otherwise indicated.

Throughout this prospectus, unless otherwise designated, the terms we, us, our, the Company and our company to Galmed Pharmaceuticals Ltd. and its subsidiaries. With respect to all financial data and the financial statements and related notes, such terms also refer to Galmed Holdings Inc. prior to the completion of the Reorganization, receipt of the Tax Pre-Ruling and consummation of this offering, each as defined under Prospectus Summary Corporate Information, Business Historical Background and Corporate Structure and Israeli Tax Considerations Pre-Ruling Regarding a Reorganization of Our Corporate Structure, as applicable, and as further described elsewhere in this prospectus.

EXPLANATORY NOTE

Market data and certain industry data and forecasts used throughout this prospectus were obtained from internal company surveys, market research, consultant surveys commissioned by the Company, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys commissioned by the Company and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. However, this information may prove to be inaccurate because of the method by which some of the data for the estimates is obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. As a result, the market and industry data and forecasts included or incorporated by reference in this prospectus, and estimates and beliefs based on that data, may not be reliable. We have relied on certain data from third-party sources, including internal surveys, industry forecasts and

market research, which we believe to be reliable based on our management s knowledge of the industry. However, we have not ascertained the underlying economic assumptions relied upon therein. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not necessarily know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements as to our market position are based on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this prospectus, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading Risk Factors in this prospectus. Notwithstanding the foregoing, we remain responsible for the accuracy and completeness of the historical information presented in this prospectus, as of the date of the prospectus.

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PROSPECTUS SUMMARY

This summary highlights selected information presented in greater detail elsewhere in this prospectus. This summary does not include all the information you should consider before investing in the Shares. You should read this summary together with the more detailed information appearing in this prospectus, including our audited financial statements and related notes and the sections entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations.

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of a novel, once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones utilizing our proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. We believe that our product candidate, aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, including Non-Alcoholic Steato-hepatitis, or NASH, which is a chronic disease that constitutes a large unmet medical need. NASH is a severe form of Non-Alcoholic Fatty Liver Disease, or NAFLD, which is characterized by inflammation in the liver in addition to the presence of excess liver fat. NASH is often discovered incidentally, often times by elevated liver enzyme levels in blood tests. NASH patients may be asymptomatic or suffer from fatigue, with other symptoms occurring as the liver disease advances. As the disease progresses, persistent fatty infiltration and inflammation cause liver damage marked by fibrosis and the gradual loss of normal liver cells, which dramatically increases the risk of late-stage severe liver diseases, such as cirrhosis, carcinoma and end-stage liver disease, each potentially requiring liver transplantation. In addition to its serious hepatic complications, NASH is also associated with an increased risk of cardiovascular complications, adding to the risks associated with metabolic syndrome. Metabolic syndrome is a serious health condition caused by obesity, physical inactivity and genetic factors that results in a higher risk of cardiovascular disease, diabetes, stroke and NASH. Patients with NASH have an increased overall mortality rate, as compared to control populations, and independent third-party epidemiological studies have shown that such increased mortality is a result of liver-related mortality and a higher risk of cardiovascular disease associated with NASH, independently of the risks associated with metabolic syndrome.

We are initially developing aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance. These patients are at the highest risk of developing both the cardiovascular and hepatic complications associated with NASH. Aramchol is a first-in-class conjugate of cholic acid, or a type of bile acid, and arachidic acid, or a type of saturated fatty acid. The conjugated molecule acts upon important metabolic pathways and has been shown in a 60-patient Phase IIa clinical trial to reduce fat accumulation in the liver as well as regulate the transport of cholesterol, which is essential for maintaining cholesterol balance in the body. Independent third-party epidemiologic studies have shown that fat reduction reduces, and eventually eliminates, liver inflammation in patients who have undergone bariatric surgery or other weight loss programs. We believe that aramchol s ability to reduce liver fat without observable adverse side effects in our studies to date will be central in the treatment of NASH and the hepatic and cardiovascular complications associated therewith. In the near future, we intend to submit an Investigational New Drug, or IND, application to the U.S. Food and Drug Administration, or the FDA, regarding aramchol, which, if approved, would allow us to conduct part of our clinical development in the United States.

During the second half of 2014, we intend to begin a multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase IIb clinical trial of aramchol in 240 NASH patients who also suffer from obesity and insulin resistance. Our development of aramchol to date has been deemed appropriate by the FDA, the United Kingdom s Medicines and Healthcare Products Regulatory Agency, or MHRA, Germany s Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM, and deemed satisfactory by France s Agence Nationale de Sécurité du Médicament et des Produits de Santé, or ANSM. Our planned Phase IIb clinical trial for aramchol in NASH patients is in accordance with the study design recommended by the MHRA, deemed acceptable by BfArM, and deemed satisfactory by ANSM.

Recently, the FDA confirmed in a written pre-IND advisory letter that such study design is acceptable for a Phase IIb study. BfArM and ANSM also confirmed, in minutes of each of their respective scientific advisory meetings, that if successful, this Phase IIb trial may serve as a basis for Phase III pivotal trials of aramchol. The FDA and MHRA invited us to discuss the next steps in the development of aramchol after the results of the Phase IIb study are analyzed. If the Phase III trials are successful, we intend to submit a New Drug Application, or NDA, to the FDA and a Marketing Authorization Application, or MAA, to the EMA for the approval of aramchol for the treatment of NASH in

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patients who also suffer from obesity and insulin resistance in the United States and Europe. We currently expect results from the Phase IIb trial to be available in the second half of 2016. During this Phase IIb trial, and once 120 patients complete six months of treatment, we intend to conduct an interim analysis of the efficacy and safety of aramchol based on blood markers of inflammation. We currently expect results from the interim analysis to be available in the second half of 2015. We also currently plan to conduct, but provide no assurance that we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of NASH in children, which will be preceded by further preclinical studies and pharmacokinetic, or PK, studies, and an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones.

To date, we have successfully completed three clinical trials of aramchol. The first was a single dose, placebo-controlled, double-blind Phase Ia study with ascending doses of aramchol in healthy volunteers in one center in Israel. All doses proved to be well-tolerated, and no adverse side effects were observed in our studies to date. An additional Phase Ib repeated dose trial completed in healthy volunteers in one center in Israel also showed that aramchol has no significant observable adverse side effects at the doses tested and confirmed the suitability of a once-daily dose of aramchol. A multi-center, randomized, double-blind, placebo-controlled Phase IIa trial of aramchol in 60 NAFLD and NASH patients in 12 centers in Israel, whose study design was deemed acceptable by the FDA in 2007 at a pre-IND scientific advisory meeting, demonstrated that aramchol reduced liver fat in a dose dependent manner, as evidenced by a statistically significant reduction of liver fat measured by Nuclear Magnetic Resonance Spectroscopy, or NMRS, which measures tissue chemical components, over a three month treatment period of once-daily 300 mg doses of aramchol, and induces positive trends in several metabolic parameters. We have submitted the Phase IIa study results for publication in a peer reviewed medical journal and expect such results to be published in 2014. The following diagram illustrates the clinical trials that we have completed to date and those that we intend to undertake with respect to aramchol for NASH patients who also suffer from obesity and insulin resistance.

Aramchol: Results to date in, and future objectives of, clinical trials

According to the Journal of Gastroenterology and Hepatology in 2013, NAFLD is believed to affect up to 30% of the population in developed countries and up to 75% of Western populations with diabetes and obesity. Also according to the Journal of Gastroenterology and Hepatology in 2013, approximately 12% of the general population in the United States and in the five most-populated countries in the European Union, or EU, the United Kingdom, France, Spain, Germany and Italy, has NASH. According to the Journal of

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Hepatology in 2008, and as summarized in the Journal of Hepatology in 2010, the risk that persons with NASH will suffer a liver disease-related death is ten-times higher than that of the general population, and according to these sources, as well as the Journal of Gastroenterology in 2005, NASH increases overall mortality by between 35% and 85%. Additionally, according to the Journal of Gastroenterology and Hepatology in 2013, approximately one third of all NASH patients will develop liver cirrhosis, and nearly one million people with NASH are projected to progress to liver cirrhosis between 2006 and 2015. According to the Journal of Gastroenterology in 2011, the proportion of liver transplants attributed to NASH in the United States increased from 1.2% in 2001 to 9.7% in 2011, establishing NASH as the third leading cause of liver transplantation in the United States. Furthermore, according to the Journal of Digestive Diseases in 2011 and the Journal of Hepatology in 2010, NASH will become the leading cause of liver transplantation in the United States by 2020. Michael Charlton and other scientists at the Mayo Clinic project NASH to surpass hepatitis C as the leading cause of hepatocellular carcinoma in the near future. NASH patients are also twice as likely to die from cardiovascular disease as the global general population.

According to GlobalData, the growing global rate of obesity and diabetes, as well as the expected launch of new NASH specific treatments, will increase the NASH market from $233.0 million in off-label sales in the United States and the five most-populated EU countries in 2012 to $863.0 million in total sales by 2017, with a compounded annual growth rate, or CAGR, of 30%. Based on our extrapolation from the estimated total direct economic cost over the respective lifetimes of the current NASH population in the United States aged 45 to 74, which cost was presented in the Journal of Hepatology in 2006, we estimate that the financial burden of NASH in the United States alone may reach approximately $41 billion within the next decade. Furthermore, according to studies published in the Journal of Gastroenterology in 2008, the progression to NASH increases the five year direct and indirect healthcare costs for patients with NAFLD by 26%.

We believe that aramchol s ability to reduce liver fat content without observable adverse side effects in our studies to date, and convenient once-daily oral administration make aramchol a potentially valuable drug for the treatment of NASH and cholesterol gallstones and the potential prevention of severe hepatic and cardiovascular complications associated with NASH, including cirrhosis and carcinoma, that would otherwise lead to liver transplantation. Aramchol has not been approved for commercial sale or marketing and, to date, there have been no commercial sales of aramchol.

Our Development Pipeline

The table below sets forth our current pipeline with respect to aramchol, including target indications and the current phase of development for each such indication.

Indication	Planned Next Clinical Trial	Expected Number of Patients	Anticipated Key Events
Non-Alcoholic Steatohepatitis (NASH)	Phase IIb	240 patients	Initiate Phase IIb trial in the second half of 2014

			Conduct interim analysis of 120 patients in Phase IIb trial who have completed six months of treatment in the second half of 2015
			Release top-line results from Phase IIb trial in the second half of 2016
Cholesterol Gallstones	Phase IIa	20 patients	Initiate Phase IIa trial in the second half of 2014
			Release top-line results from Phase IIa trial in the second half of 2014
NASH in Children	Preclinical	To be determined	Pediatric Investigational Plan submission in the first half of 2014
			Initiate Phase I trial in the second half of 2015

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In addition to NASH in adults, we intend to pursue other indications in our aramchol development program, including the treatment of NASH in children, cholesterol gallstones, chemotherapy-associated steatohepatitis, or CASH, and feline hepatic lipidosis, or feline fatty liver.

We are also collaborating with Enterome Bioscience, a French company, or Enterome, on the development of a non-invasive biomarker which, if successful, would predict individual responses to aramchol. Currently, liver biopsy is the standard approach for the diagnosis of inflammation and fibrosis associated with NASH. However, use is limited due to the procedure-related morbidity, sample errors and costs. We believe that the current lack of specific and non-invasive diagnostic tools for NASH presents a major challenge to the scientific and medical communities. Both preventive care and treatment depend on an accurate diagnosis of NASH, with a biopsy being the only diagnostic method currently available, thus limiting patient care and prognosis. Enterome is developing a non-invasive proprietary test seeking to stratify patients according to their bacterial gut composition. We intend, as part of our Phase IIb study of aramchol, to correlate the findings of Enterome s test with liver biopsies in the patients enrolled in our studies in order to explore and validate the test as a biomarker based on the profiling of patients treated with aramchol. We will not receive any financial payment from Enterome and we are not obligated to make any financial payment to Enterome in respect of such activities. We agreed to enter into a definitive agreement with Enterome on the basis of the principles detailed in a certain memorandum of understanding, but no such definitive agreement has been executed as of yet.

We also intend to collaborate, as part of our Phase IIb study of aramchol, with a Finnish company working on lipidomics, Zora Biosciences Oy, or Zora, in order to identify the profile of NASH patients responding to aramchol treatment. We will not receive any financial payment from Zora in respect of such activities. We agreed to enter into a definitive agreement with Zora on the basis of the principles detailed in a certain memorandum of understanding, but no such definitive agreement has been executed as of yet.

We hope that these efforts will lead to the identification of a specific biomarker which will differentiate NASH from NAFLD patients without the need for liver biopsy, and serve as a tool for the prediction and assessment of aramchol s efficacy. We believe that the identification of such a specific biomarker may facilitate the market penetration of aramchol however, we do not expect to generate any revenue directly from such biomarker.

Our Competitive Strengths

We believe we are strategically positioned to address the unmet medical needs of NASH patients who also suffer from obesity and insulin resistance. Our competitive strengths include:

A once-daily oral drug without observable adverse side effects in development for the chronic treatment of NASH. We believe that the characteristics of aramchol, including its ability to reduce liver fat content without observable adverse side effects in our studies to date, which we believe may result in an anti-inflammatory effect, its ability to modulate the transport of cholesterol in the body and its simple and convenient delivery through once-daily oral administration, position it well against the competition in the treatment of NASH. We believe that such characteristics may also lead to aramchol's acceptance and adoption by the medical community, including patients, as an alternative to the medical treatments used today, which are not approved by applicable regulatory authorities for NASH as their efficacy has not been proven in well-designed clinical studies. We believe aramchol is well-positioned against drugs in development for NASH, some of which may require intravenous delivery or may cause adverse events, such as itching, which can be highly inconvenient for patients with chronic diseases, such as NASH, and may result in low patient compliance.

Extensive knowledge and expertise in the treatment of liver diseases, the development of FABACs and working with lipid molecules. We believe our management team, scientific advisors, personnel and affiliates, including our subsidiaries, have extensive knowledge and experience in the treatment of liver diseases and cholesterol gallstones, developing FABACs, such as aramchol, for the treatment of liver diseases and cholesterol gallstones and working with lipid molecules, which due to their special physiochemical characteristics, are difficult to synthesize,

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develop and work with. We believe that such knowledge and expertise makes us competitive in the NASH and cholesterol gallstones fields.

Non-invasive diagnostic tools for the assessment of aramchol s effect. If we are successful in our clinical trials in correlating fat reduction in the liver as measured by NMRS, an FDA validated and commonly used test for the measurement of liver fat content, with aramchol s effect on inflammation in the liver, NMRS may become a non-invasive biomarker that is able to measure the effect of aramchol in patients following treatment with the drug. Additionally, in collaboration with Enterome, we intend to develop a non-invasive biomarker that is able to predict individual responses to aramchol prior to treatment and permit follow-up monitoring of the effect of aramchol in a particular patient. We also are collaborating with Zora in order to identify the lipidomic profile for NASH patients responding to aramchol treatment. We believe that such biomarkers and profiles may facilitate aramchol's market penetration and accelerate its acceptance and adoption by the medical community and NASH patients as a treatment option, thereby increasing our competitiveness in the NASH market.

Our Strategy

Our strategy is to build a specialized biopharmaceutical company that discovers, develops and commercializes novel FABAC drugs and other lipid molecules for the treatment of liver diseases and cholesterol gallstones, beginning with the treatment of fatty liver disorders, primarily NASH, and cholesterol gallstones. Key elements of our strategy include:

Continuing to advance our development of aramchol for the treatment of NASH. Our development of aramchol for the treatment of NASH currently includes the planned Phase IIb trial of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance. If our planned Phase IIb trial is successful, the results will serve as a basis for potential Phase III pivotal trials in Europe and Israel for the same indication and as a basis for discussion for potential Phase III pivotal trials in the United States for the same indication.

Exploring other indications for the use of aramchol, which currently includes the treatment of NASH in children and cholesterol gallstones. We currently plan to conduct, but provide no assurance that we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of NASH in children and an open-label Phase IIa proof-of-concept clinical trial of aramchol for the cholesterol gallstones.

Establishing a development and commercialization partnership for aramchol if we successfully complete the Phase IIb trial or after the successful completion of the first of the potential Phase III trials of aramchol for the treatment of NASH. Following applicable regulatory approval, which we provide no assurance we will receive, we intend to commercialize aramchol, and our other future products, through out-licensing agreements with major pharmaceutical or biotechnology companies that possess experience, resources and infrastructure to execute a successful market launch and provide sales support for aramchol. We may ultimately, in the future, consider building an internal commercial infrastructure.

Advancing existing collaborations for the discovery and validation of diagnostic tools and biomarkers for the diagnosis of liver disease. We intend to advance our existing collaborations and strategic arrangements for the discovery and validation of non-invasive diagnostic tools and biomarkers for the diagnosis of liver disease, including NASH.

In-licensing or acquiring additional drug candidates for the treatment of liver diseases. Aramchol is directed at the treatment of liver diseases, particularly NASH, that have major global markets and cholesterol gallstones. Our intent is to explore opportunities to in-license or acquire other drugs and/or drug conjugates for the treatment of liver diseases.

Risk Factors

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 and carefully consider these risks, together with the risks set forth under the section entitled Risk Factors and all of the other information in this

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prospectus, including the 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 in this prospectus actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. In particular, our risks include, but are not limited to, the following:

We are a clinical-stage biopharmaceutical company with a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

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

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations. If additional capital is available, raising such capital may be costly or difficult to obtain and will dilute our current shareholders ownership interests.

We depend entirely on the success of our product candidate, aramchol, and we may not obtain regulatory approval of aramchol.

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

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

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

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

Lack of a reliable non-invasive method for the diagnosis of NASH is likely to present a major challenge to our product candidate s market penetration, if ever commercialized.

We have no manufacturing capacity and anticipate reliance on third-party manufacturers for our products.

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

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

Corporate Information

Our Company was incorporated in Israel on July 31, 2013 as an Israeli privately held company. However, our business has been operating since 2000 under a different group of companies established in the same year, or the Group. Originally, we operated under the parent company, Galmed Holdings Inc., or GHI, a holding company incorporated in the British Virgin Islands. GHI held all of the rights in Galmed 2000 Inc., or GTTI, also a holding company incorporated in the British Virgin Islands. GTTI held substantially all of the rights in Galmed International Limited, or GIL, which is incorporated in Malta, an EU member state (other than one share held by GRD for our benefit). GIL held all of the rights in Galmed Medical Research Ltd., or GMR, an Israeli company. Our intellectual property was held by GIL. The research and development was conducted by GMR as a service to GIL on a cost plus basis. GIL was responsible for all product development.

On February 2, 2014, we underwent a reorganization, or the Reorganization, pursuant to which all of our business, including our intellectual property, was transferred to the Company. The Group was reorganized by share transfers and asset transfers, resulting in the Company as the parent company and 100% equity-owner of the following companies: (1) Galmed Research and Development Ltd., or GRD, a newly formed Israeli company, which holds all the Group s intellectual property, including the Company s patent portfolio; (2) GIL, which may provide research and development services to GRD on a cost plus basis; and (3) GTTI, which is

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an inactive company that we expect to liquidate at or following the end of 2015. GIL holds GMR, which will become an inactive company before the end of 2014. For a more detailed description of the Reorganization see Business Historical Background and Corporate Structure below.

Immediately prior to the Reorganization, all our shareholders collectively held 9,739 ordinary shares of GHI. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to all such shareholders ordinary shares of the Company, such that upon the Reorganization all our shareholders collectively held 7,099,731 ordinary shares of the Company, in the same proportion among all shareholders, which reflected a ratio of 729 ordinary shares of the Company for each ordinary share of GHI.

In connection with the Reorganization, we obtained a pre-ruling from the Israeli Tax Authority, or the Tax Pre-Ruling, which includes certain restrictions and limitations, as detailed in Taxation Israeli Tax Considerations below.

Our principal executive offices and registered office in Israel are located at 8 Shaul Hamelech Blvd., Amot Hamishpat Bldg., Tel Aviv, Israel, and our telephone number is +972 3-6938448. Our website address is *http://www.galmedpharma.com*. Following the completion of this offering, we will post on our website any materials required to be posted on such website under applicable securities laws and regulations, including posting any XBRL interactive financial data required to be filed with the SEC, and notices of general meetings of our shareholders. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into 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, as amended, 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.

Lastly, upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act of 1934, as amended, or the Exchange Act, that are applicable to foreign private issuers, and under those requirements we will file reports with the U.S. Securities and Exchange Commission, or SEC. Those other reports, or other information, may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Although we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act, we intend to do so. As such, we will file with the SEC, within 90 days after the end of each fiscal year, or such other 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 within 45 days after the end of each of the first three fiscal quarters, or such other applicable time as required by the SEC, unaudited quarterly financial information on Form 6-K. We also intend to furnish to the SEC under cover of Form 6-K certain other material information.

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THE OFFERING

Offering Summary

Issuer

Galmed Pharmaceuticals Ltd.

Ordinary Shares Offered

2,837,400 Shares

Ordinary Shares Outstanding Before Offering

7,659,955 shares

Ordinary Shares to be Outstanding Immediately After Offering

10,674,843 shares (which includes the ordinary shares issuable upon exercise of the Warrant (as defined below))

Offering Price

$13.50 per Share

Underwriter s Over-Allotment Option

The Underwriting Agreement provides that we granted to Maxim Group LLC, the sole book-running manager of the offering, an option, exercisable within 45 days after the closing of this offering, to acquire up to an additional 425,610 Shares, solely for the purpose of covering over-allotments.

Use of Proceeds

The net proceeds to us from this offering will be approximately $34,385,199 (or $39,728,733 if the underwriters exercise their over-allotment option in full), based upon the initial public offering price of $13.50 per Share after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering as follows: (i) for clinical trials and product development, including approximately $10.0 million for the initiation and completion of the Phase IIb clinical trial of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance; (ii) approximately $5.0 million for establishing and building a research and development infrastructure in the United States, including hiring a new vice president for North America; (iii) approximately $5.0 million for conducting other studies in connection with the product candidate, including but not limited to, PK studies and food effect studies, and (iv) for working capital and general corporate purposes of the Company. Pending such usage, we expect to invest the proceeds in short-term interest-bearing instruments. See Use of Proceeds below.

Dividend Policy

We do not anticipate declaring or paying any cash dividends on our ordinary shares following this offering.

Risk Factors

Investing in the Shares involves a high degree of risk. You should carefully read and consider the information set forth under the heading Risk Factors and all other information set forth in this prospectus before deciding to invest in the Shares.

Lock-up

We, our directors, executive officers and certain of our existing shareholders have agreed with the underwriters not to offer, issue, sell, contract to sell, encumber, grant

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any option for the sale of or otherwise dispose of any of our securities for a period of 180 days following the closing of the offering of the Shares, subject to certain exceptions. See Underwriting for more information. In addition, the holders of substantially all of our outstanding shares and options have agreed, in accordance with the terms of the Tax Pre-Ruling, not to sell or dispose of our ordinary shares for a period of two years following the consummation of the Reorganization, subject to certain exceptions. See Taxation Israeli Tax Considerations Pre-Ruling Regarding a Reorganization of Our Corporate Structure below.

Nasdaq Capital Market Trading Symbol GLMD

The number of our ordinary shares to be outstanding immediately after this offering is based on 7,659,955 ordinary shares outstanding as of February 27, 2014 and 177,488 ordinary shares issuable upon the exercise of a warrant granted under our 2013 Plan to our Chairman, Mr. Chaim Hurvitz, or the Warrant, which will be exercised automatically upon the completion of this offering, by way of cashless exercise, based upon the initial public offering price of $13.50 per Share. This number excludes 1,298,173 ordinary shares issuable upon the exercise of share options outstanding as of February 27, 2014 under our 2013 Incentive Share Option Plan, or our 2013 Plan, 17,166 ordinary shares issuable upon the exercise of options which will be granted upon the consummation of the offering under our 2013 Plan to Mr. Marth, 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and 784,304 ordinary shares reserved for future grants under our 2013 Plan. These issued options have a weighted average exercise price of $1.28 per share and expire in September 2023, with the exception of the option to purchase 38,637 shares granted to the service provider, which has no expiration date.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

the filing of our amended and restated articles of association, or our Articles, which will occur immediately prior to the completion of this offering; and

no exercise of the underwriters over-allotment option or the representative s warrants, or the Representative s Warrants.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our financial data (which reflects the financial data of GHI, our predecessor, prior to the Reorganization). We have derived the following statements of operations data for the years ended December 31, 2013, 2012 and 2011, as well as the balance sheet data as of December 31, 2013 and 2012 from our audited consolidated 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 consolidated 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.

	Year ended December 31,		
	2011	2012	2013
	(In thousands, except share and per share data)		
Statements of Operations Data:			
Research and development expenses	$1,326	$2,443	$7,207
General and administrative expenses	151	694	7,355
Capital Loss			10
Operating loss	1,477	3,137	14,572
Financial expenses, net	3	6	2,912
Operating loss post-finance expense & other income, net	1,480	3,143	17,484
Taxes on income	2	6	1
Net loss	$1,482	$3,149	$17,485
Deemed dividend	0	0	
Net loss per share	$216.26	$459.51	$2,514.38
Weighted average number of ordinary shares used in computing basic and diluted net loss per share[1]	6,853	6,853	6,954

(1) See Note 2 to our consolidated financial statements for the year ended December 31, 2013, 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.

	As of December 31, 2013		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
		(unaudited)	(unaudited)
	(In thousands, except per share data)		
Balance Sheet Data:			
Cash and cash equivalents	$ 137	$ 2,137	$ 36,768
Working capital	(1,536)	464	35,095
Total assets	166	2,166	36,797
Total liabilities	2,117	2,117	2,117
Shareholders equity (deficit)	(1,951)	49	34,680

(1)

The unaudited pro forma column in the balance sheet data above gives effect to (i) the issuance of 560,224 ordinary shares for a total consideration of $2.0 million that took place on February 3, 2014 and (ii) to the exercise of the Warrant upon the closing of the offering.

(2) The unaudited pro forma as adjusted column in the balance sheet data above gives effect to footnote (1) above as well as the sale of 2,837,400 Shares in this offering at the initial public offering price of $13.50 per Share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, as if the sale had occurred on December 31, 2013.

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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 carefully consider the factors described below, together with all of the other information in this prospectus, including the audited 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 Our Financial Position and Capital Requirements

We are a clinical-stage biopharmaceutical company with a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

We are a clinical-stage biopharmaceutical company with a limited operating history and no approved products. To date, we have focused almost exclusively on developing our product candidate, aramchol. We have funded our operations to date primarily through proceeds from the private placement of ordinary shares and convertible debt. 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 no products and have not generated any revenue from product sales to date. We have incurred losses in each year since the inception of our predecessor in 2000. Our loss attributable to holders of our ordinary shares for the years ended December 31, 2012 and 2013 was approximately $3.1 million and $17.5 million, respectively. As of December 31, 2013, we had an accumulated deficit of $27.6 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 clinical trials. In addition, if we obtain marketing approval for aramchol, we will likely initially incur significant outsourced sales, marketing and manufacturing expenses, as well as continued research and development expenses. Furthermore, in the period following this offering, we expect 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.

Our limited operating history makes it difficult to evaluate our business and prospects.

We have a limited operating history and our operations to date have been limited primarily to research and development, raising capital and recruiting scientific and management personnel and third-party partners. As such, it may be difficult to evaluate our business and prospects. We have not yet demonstrated an ability to commercialize or

obtain regulatory approval for any product candidate. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development and/or commercialize our product candidate, or any future product candidate, obtain regulatory approvals or achieve market acceptance or favorable pricing for our product candidate or any future product candidate.

Our limited operating history makes it difficult to evaluate our business andprospects. 23

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

Our ability to become profitable depends upon our ability to generate revenue in excess of our expenses. To date, we have not generated any revenue from our development stage product candidate, aramchol, or any other product candidate. We do not know when, or if, we will generate any revenue. We do not expect to generate revenue unless and until we obtain regulatory and marketing approval of, and commercialize, aramchol. We will continue to incur research and development and general and administrative expenses related to our operations. As of December 31, 2013, the Company had an accumulated deficit of approximately $27.6 million. We expect to continue to incur losses for the foreseeable future, and these loses will likely increase as we:

initiate and manage preclinical development and clinical trials for our current and any new product candidates;
seek regulatory approvals for our product candidate, or future product candidates, if any;
implement internal systems and infrastructures;
seek to in-license additional technologies to develop;
hire additional management and other personnel; and
move towards commercialization of our product candidate and future product candidates, if any.

We may out-license our ability to generate revenue depending on a number of factors, including our ability to:

obtain favorable results from and progress the clinical development of aramchol;
develop and obtain regulatory approvals in the countries and for the uses we intend to pursue for aramchol;
subject to successful completion of registration, clinical trials and perhaps additional clinical trials of aramchol, apply for and obtain marketing approval in the countries we intend to pursue for aramchol;
contract for the manufacture of commercial quantities of aramchol at acceptable cost levels if marketing approval is received; and
establish external, and potentially in the future, internal, sales and marketing capabilities to effectively market and sell aramchol in the United States and other countries.

Even if aramchol is approved for commercial sale for the treatment of NASH in patients who also suffer from obesity and insulin resistance, or any other indications, 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 additional funding.

We have not yet commercialized any products and we may never become profitable.

We have not yet commercialized any products and we may never be able to do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance for appropriate indications at favorable reimbursement rates. The degree of market acceptance of these products will depend on a number of factors, including:

the timing of regulatory approvals in the countries, and for the uses, we intend to pursue with respect to the commercialization of our product candidates;
the competitive environment;

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the acceptance by the medical community of the safety and clinical efficacy of our products and their potential advantages over other therapeutic products;

the development of a non-invasive diagnostic biomarker for the detection of NASH;

the adequacy and success of distribution, sales and marketing efforts, including through strategic agreements with pharmaceutical and biotechnology companies; and

the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend, and in the case of third-party payors, cover any of our products. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products, we may not become profitable.

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

We will need to raise substantial additional capital to fund our operations and to develop and commercialize aramchol. As of December 31, 2013, we had a negative working capital of $1.5 million and cash and cash equivalents of $137,000. Our future capital requirements may be substantial and will depend on many factors including:

our clinical trial results;

the cost, timing and outcomes of seeking marketing approval of aramchol;

the cost of filing and prosecuting patent applications and the cost of defending our patents;

the cost of prosecuting infringement actions against third parties;

exploration and possible label expansion of aramchol for the treatment of other conditions or indications;

the costs associated with commercializing aramchol if we receive marketing approval, including the cost and timing of establishing external, and potentially in the future, internal, sales and marketing capabilities to market and sell aramchol;

subject to receipt of marketing approval, revenue received from sales of approved products, if any, in the future;

any product liability or other lawsuits related to our future product candidates or products, if any;

the demand for our products;

the expenses needed to attract and retain skilled personnel; and

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, through 2016. We believe these funds will enable us to complete any preparatory clinical and non-clinical work, as well as the Phase IIb clinical trial of aramchol for the treatment of NASH patients who also suffer from obesity and insulin resistance. We will require significant additional funds to initiate and complete the FDA and EMA approval process. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, such as losing our Small and Medium Enterprise status at the EMA, which entitles us to significant fee reductions. Because the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenditures associated with our anticipated clinical trials. 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

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, re

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available to us on a timely basis, or at all, we may be required to terminate or delay planned clinical trials or other development activities for aramchol and the Phase III clinical trials.

Raising additional capital may be costly or difficult to obtain and will dilute current shareholders ownership interests.

Any debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our technologies, products or marketing territories. If we are unable to obtain required additional capital, we may have to curtail our growth plans or cut back on existing business, and we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

Any additional capital raised through the sale of equity or equity-linked securities may dilute our current shareholders ownership in us and could also result in a decrease in the market price of our ordinary shares. The terms of those securities issued by us in future capital transactions may be more favorable to new investors and may include the issuance of warrants or other derivative securities, which may have a further dilutive effect.

We are unable to estimate our long-term capital requirements due to uncertainties associated with the development and commercialization of our product candidate. If we fail to obtain necessary funds for our operations, we will be unable to maintain and improve our intellectual property and technology, and we will be unable to develop and commercialize our product candidate.

Our long-term capital requirements are expected to depend on many potential factors, including, among others:

the number of product candidates in development;
the duration and cost of discovery and preclinical development;
the regulatory path of our lead product candidate;
the results of preclinical and clinical testing, which can be unpredictable in product candidate development;
our ability to successfully commercialize our product candidates, including securing commercialization and out-licensing agreements with third parties and favorable pricing and market share;
the progress, success and cost of our clinical trials and research and development programs, including those associated with milestones and royalties;
the costs, timing and outcome of regulatory review and obtaining regulatory approval of our lead product candidate and addressing regulatory and other issues that may arise post-approval;
the breadth of the labeling assuming that our product candidate is approved for commercialization by the relevant regulatory authority, which may not occur;
our need, or decision, to acquire or in-license complementary technologies or new platform technologies or product candidate targets;
the costs of enforcing our issued patents and defending intellectual property-related claims;

the costs of investigating patents that might block us from developing potential product candidates;
the costs of recruiting and retaining qualified personnel;
our revenue, if any; and

We are unable to estimate our long-term capital requirements due touncertainties associated with the development

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our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to obtain the funds necessary for our operations, we will be unable to maintain and improve our intellectual property and technology, and we will be unable to develop and commercialize aramchol, or other product candidates, which would materially and adversely affect our business, liquidity and results of operations.

Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.

As of December 31, 2013, we had an accumulated deficit of approximately $27.6 million. Our recurring operating losses and lack of revenue raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements include a note describing the conditions which raise this substantial doubt. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve aramchol and we successfully commercialize (including out-licensing) aramchol. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. According to our estimates and based on our budget, if we are not successful in obtaining additional capital resources, there is a substantial doubt that we will be able to continue our activities beyond 2014. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

We may become subject to the payment of taxes in connection with the Reorganization.

On February 2, 2014, we underwent the Reorganization, pursuant to which all of our business (including our intellectual property) was transferred to us. The Reorganization was effected by way of share transfers and asset transfers, as follows: first, GHI transferred GTTI s entire share capital to the Company; next, GTTI transferred GIL s entire share capital to the Company; then, GIL transferred and assigned all of its intellectual property to GRD. In connection with the Reorganization, we obtained the Tax Pre-Ruling. The Tax Pre-Ruling confirms that the transfer of shares and assets resulting in the Company as the parent company and 100% equity-owner of GRD, which holds all of the Group s intellectual property, including the Company s patent portfolio, GIL and GTTI, is not taxable pursuant to the provisions of the Israeli Tax Ordinance as long as certain requirements are met. However, we have not obtained a tax pre-ruling from the tax authorities in the British Virgin Islands with respect to the transfer of the shares of GTTI and the transfer of the shares of GIL to the Company, or from the tax authorities in Malta with respect to the transfer of the intellectual property of GIL to GRD. We believe that such transfers of shares and assets are not taxable in the British Virgin Islands and Malta, respectively. However, there can be no assurance that we will not become subject to the payment of taxes in the British Virgin Islands, with respect to the transfers of shares as aforesaid, or in Malta, in connection with the transfer of the intellectual property as mentioned above. For a more detailed description of the Reorganization see Business Historical Background and Corporate Structure below.

Risks Related to Our Business, Industry and Regulatory Requirements

We depend entirely on the success of our product candidate, aramchol, and we may not obtain regulatory approval of aramchol.

We have invested almost all of our efforts and financial resources in the research and development of aramchol, 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 aramchol in a timely manner. The process to develop, obtain regulatory approval for and commercialize aramchol is long, complex, costly and uncertain as to its outcome.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drugs are subject to extensive regulation by the FDA and other regulatory agencies in other countries. These regulations

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differ from jurisdiction to jurisdiction. We are not permitted to market aramchol, or any other product candidate, in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory agencies in such countries. We have not received regulatory clearance to conduct the clinical trials that are necessary to file an NDA with the FDA or comparable applications to other regulatory authorities in other countries or received marketing approval for aramchol. The results of clinical trials may be unsatisfactory, even if we believe those clinical trials to be successful, the FDA, or other regulatory authorities, 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 receives 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 jurisdiction does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction 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 aramchol. This would reduce our target market and limit the full commercial potential of aramchol.

We might be unable to develop aramchol to achieve commercial success in a timely and cost-effective manner, or ever.

Even if regulatory authorities approve aramchol, it may not be commercially successful. Aramchol may not be commercially successful because government agencies and other third-party payors may not provide reimbursement for the costs of the product or the reimbursement may be too limited to be commercially successful; physicians and others may not use or recommend aramchol, even following regulatory approval. In addition, a product approval, assuming one issues, may limit the uses for which aramchol may be distributed thereby adversely affecting the commercial viability of the product. Moreover, third parties may develop superior products or have proprietary rights that preclude us from marketing aramchol. We also expect that aramchol will be expensive, if approved. Physician and patient acceptance of, and demand for, aramchol, if we obtain regulatory approval, will depend largely on many factors, including, but not limited to, the extent, if any, of reimbursement of costs by government agencies and other third-party payors, pricing, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with aramchol. If physicians, government agencies and other third-party payors do not accept the use or efficacy of aramchol, we will not be able to generate significant revenue, if any.

We may be forced to abandon development of aramchol, or other future product candidates, which will significantly impair our ability to generate product revenues.

Upon the completion of any clinical trial, the results might not support the claims sought by us. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that aramchol is safe and effective for the indicated uses. Any such failure may cause us to abandon aramchol and may delay development of other product candidates. Any delay in, or termination or suspension of, our clinical trials will delay the requisite filings with the FDA or other regulatory agencies and, ultimately, our ability to commercialize our product candidates and generate

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product revenues. If the clinical trials do not support our product claims, the completion of development of such product candidate may be significantly delayed or abandoned, which will significantly impair our ability to generate revenues and will materially adversely affect our results of operations.

If we acquire or in-license additional technologies or product candidates, we may incur a number of costs, may have integration difficulties and may experience other risks that could harm our business and results of operations.

We may acquire and in-license additional product candidates and technologies. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive preclinical or clinical testing, or both, and approval by the FDA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any product candidate that we develop based on acquired or in-licensed technology that is granted regulatory approval will be manufactured or produced economically, successfully commercialized or widely accepted or competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

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, a MAA to the EMA or any similar submission to regulatory authorizes in other countries. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. The fact that the FDA, EMA or other regulatory authorities permit a company to conduct human clinical trials is no guarantee that the trial will be successful. To the contrary, most candidate drugs that enter clinical trials do not prove to be successful and do not result in the filing of an NDA, MAA or similar filing. Drug candidates that prove successful at one clinical trial phase may prove unsuccessful at a subsequent phase. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Regulatory authorities, such as the FDA, may preclude clinical trials from proceeding. Additionally, the clinical trial process is time-consuming, and failure can occur at any stage of the trials. We may encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- difficulties obtaining regulatory clearance or approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties in obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

delays resulting from a decision of the FDA not to review an NDA for aramchol under the FDA s Fast Track Development Program or as a Breakthrough Therapy; and

challenges in recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size and nature of patient population, proximity of patients 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.

The commencement and completion of clinical trials can be delayed orprevented for a number of reasons35

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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 or other regulatory authorities, the institutional review boards at the sites where such boards 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:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
unforeseen safety issues or lack of effectiveness; and
lack of adequate funding to continue the clinical trials.

Although we have not experienced the risks involved with conducting clinical trials, including but not limited to, increased expense and delay, to date, there can be no assurance that we will not experience such risks in the future as we progress with our planned clinical trials.

In addition, we or regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of such trials. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop products and generate revenue.

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

Positive results in previous clinical studies of aramchol 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 preclinical studies and clinical trials for aramchol 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 believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA or EMA, or other regulatory agency, approval for their products.

Lack of a reliable non-invasive method for the diagnosis of NASH is likely to present a major challenge to our product candidate s market penetration, if ever commercialized.

Liver biopsy is the standard approach for the diagnosis of inflammation and fibrosis associated with NASH. However, the procedure-related morbidity, sample errors and costs limit its use. As such, only patients with a high risk of NASH, which includes patients with metabolic syndrome and an indication of NAFLD by non-invasive diagnostic methods, most of which are not very reliable, are sent for liver biopsy. Because NASH is mostly asymptomatic, until the disease progresses, many individuals with NASH go undiagnosed until the disease has reached its late stages. The lack of a reliable non-invasive method for the diagnosis of NASH is likely to present a major challenge to aramchol s market penetration, as many practitioners and patients may not be aware that a patient suffers from NASH and requires treatment. As such, use of aramchol might not be as wide-spread as our actual target market and this may limit the commercial potential of aramchol.

A further challenge to market penetration is that currently a liver biopsy is the standard approach for measuring improvement in NASH patients. Because it would be impractical to subject all aramchol users to regular and repeated liver biopsies, it will be difficult to demonstrate aramchol s effectiveness to practitioners and patients unless and until a reliable non-invasive method for the diagnosis and monitoring of NASH is available, as to which there can be no assurance.

Lack of a reliable non-invasive method for the diagnosis of NASH is likely topresent a major challenge to our produc

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Obtaining approval of an NDA, or other regulatory approval, 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, or similar regulatory application, is an extensive, lengthy, expensive and uncertain process, and the FDA and other regulatory agencies may delay, limit or deny approval of aramchol for many reasons, including:

we may not be able to demonstrate to the satisfaction of the applicable regulatory agencies that aramchol is safe and effective for any indication;
the results of clinical trials may not meet the level of statistical significance or clinical significance required by the applicable regulatory agencies for approval;
the applicable regulatory agencies may disagree with the number, design, size, conduct or implementation of our clinical trials;
the applicable regulatory agencies may not find the data from preclinical studies and clinical trials sufficient to demonstrate that aramchol s clinical and other benefits outweigh its safety risks;
the applicable regulatory agencies may disagree with our interpretation of data from preclinical studies or clinical trials;
the applicable regulatory agencies may not accept data generated at our clinical trial sites;
the data collected from preclinical studies and clinical trials of aramchol may not be sufficient to support the submission of an NDA or similar regulatory application;
the applicable regulatory agencies may not schedule an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the applicable regulatory agencies require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
the applicable regulatory agencies may require development of a risk evaluation and mitigation strategy as a condition of approval;
the applicable regulatory agencies may require simultaneous approval for both adults and children which would delay needed approvals, or we may have successful clinical trial results for adults, but not children, or vice versa;
the applicable regulatory agencies may change their approval policies or adopt new regulations that may impede consideration or approval of our NDA, or similar regulatory application;
the applicable regulatory agencies may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers, or suppliers of active pharmaceutical ingredients, or APIs, with which we enter into agreements for clinical and commercial supplies; and
the applicable regulatory agencies may demand post-marketing approval studies, such as Phase IV clinical trials, in connection with aramchol.

Before we can submit an NDA, or similar regulatory application, to the FDA, or other regulatory authorities, as applicable, we must conduct a Phase IIb clinical trial and pivotal Phase III clinical trials that will be substantially broader than our Phase IIa trial. We will also need to agree on a protocol with the FDA for the clinical trials before commencing those trials in the United States. Phase III 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 applicable regulatory agencies 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 considering or reconsidering the NDA or similar regulatory application. 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

Obtaining approval of an NDA, or other regulatory approval, even after clinical trials that are believed to be success

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available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the applicable regulatory agencies to provide regulatory approval. If any of these outcomes occur, we would not receive approval for aramchol and may be forced to cease operations.

Even if we obtain regulatory approval for aramchol, the approval might contain significant limitations related to the intended uses for which the drug is approved, use restrictions including, without limitation, for certain labeled populations, 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 aramchol, we may be forced to cease operations.

Aramchol may produce undesirable side effects that we may not detect in our clinical trials, which could prevent us from achieving or maintaining market acceptance of this product candidate and could substantially increase commercialization costs or even force us to cease operations.

Even if aramchol receives marketing approval, we or others may later identify undesirable side effects caused by the product, and in that event, a number of potentially significant negative consequences could result, including:

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

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.

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 adversely affect the cost, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for aramchol would be harmed and our ability to generate product revenue would be delayed, possibly materially.

We cannot be certain that the results of our Phase III clinical trials, even if all endpoints are met, will support regulatory approval of aramchol for the treatment of NASH.

Currently, the FDA and other regulatory agencies do not have any clear guidance on which endpoints of a Phase III clinical trial would be sufficient for approval of a drug for the treatment of NASH. Therefore, the development pathway for aramchol is not completely clear beyond Phase IIb, for which the measurement of liver fat content by NMRS is an endpoint validated by the FDA.

For example, the FDA recognizes that because NASH is characterized by a long asymptomatic natural history, it may be difficult to demonstrate efficacy in a Phase III clinical trial. However, it is precisely this type of demonstration, evidencing the substantive evidence of effectiveness of a drug, that is required for drug approval.

In certain limited and rare circumstances, the FDA permits drug developers to use a surrogate endpoint to demonstrate the clinical benefits of their drugs in the short term, the demonstration of which is sufficient

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for initial marketing approval. A surrogate endpoint is defined as a biomarker that is intended to substitute for a clinical endpoint, and which is expected to predict the clinical benefit or harm associated with a drug. Once marketing approval has been received, the drug developer is required to conduct post-approval clinical trials that demonstrate clinical benefit.

Although the FDA has indicated at a workshop held in association with the American Association for the Study of Liver Diseases, or AASLD, that an acceptable surrogate endpoint for drugs targeting the early stages of NASH (i.e., fat infiltration and inflammation, as opposed to fibrosis) is clearance or improvement of NASH in liver biopsy, this has not been confirmed by any formal guidelines. It is possible that even if the results of our Phase III clinical trial demonstrate the clearance or improvement of NASH in liver biopsy, the FDA will require longer-term studies of aramchol prior to granting marketing approval.

Even if aramchol, or any other product candidate that we may develop, receives marketing approval, we will continue to face extensive regulatory requirements and any such product may still face future development and regulatory difficulties. In addition, we are subject to government regulations and we may experience delays in obtaining required regulatory approvals to market our proposed product candidates.

Even if we receive regulatory approval to market a particular product candidate, any such product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed over time after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved products from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the FDA, and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

suspend or impose restrictions on operations, including costly new manufacturing requirements;
refuse to approve pending applications or supplements to applications;
suspend any ongoing clinical trials;
suspend or withdraw marketing approval;
seek an injunction or impose civil or criminal penalties or monetary fines;
seize or detain products;
ban or restrict imports and exports;
issue warning letters or untitled letters;
suspend or impose restrictions on operations, including costly new manufacturing requirements; or
refuse to approve pending applications or supplements to applications.

Even if aramchol, or any other product candidate that we may develop, receives marketing approval, we will continu

In addition, various aspects of our operations are subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

Even if aramchol, or any other product candidate that we may develop, receives marketing approval, we will continu

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Delays in regulatory approval, limitations in regulatory approval and withdrawals of regulatory approval may have a material adverse effect on the Company. If we experience significant delays in testing or receiving approvals or sign-offs to conduct clinical trials, our product development costs or our ability to out-license product candidates will increase.

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

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

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

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 aramchol and any other future product candidate. 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 aramchol, sales will be limited unless the product achieves broad market acceptance.

The commercial success of aramchol and any other future product candidate for which we obtain marketing approval from the FDA, or other regulatory authorities, will depend on the breadth of its approved labeling and 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:

demonstration of clinical safety and efficacy compared to other products;
ability of physicians to accurately diagnose NASH in its early stages;
the relative convenience and ease of administration;

If we receive marketing approval for aramchol, sales will be limited unless theproduct achieves broad market accep

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the prevalence and severity of any adverse side effects;
limitations or warnings contained in the product s approved labeling;
distribution and use restrictions imposed by the FDA, or other regulatory agencies, or agreed to by us as part of a mandatory or voluntary risk management plan;
availability of alternative treatments, including, in the case of aramchol, a number of competitive products already approved or expected to be commercially launched in the near future;
pricing and cost effectiveness;
the effectiveness of our, or any future collaborators , sales and marketing strategies;
our ability to obtain sufficient third-party coverage or reimbursement; and
the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage.

If aramchol 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 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 such regulatory agencies for aramchol may also include restrictions on use. Such regulatory agencies may impose further requirements or restrictions on the distribution or use of aramchol 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 aramchol, physicians may nevertheless prescribe aramchol 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. In particular, the U.S. 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.

We may be subject to extensive environmental, health and safety, and other laws and regulations in multiple jurisdictions.

Our business involves the controlled use, through our service providers, of hazardous materials, various biological compounds and chemicals, and as such, we, our agents and our service providers may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any environmental and health laws or

regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs incurred by us to install new or updated pollution control equipment for our service providers, modify our operations or perform other corrective actions at our facilities or the facilities of our service providers. In addition, fines and penalties may be imposed on us, our agents and/or our service providers for noncompliance with environmental, health and

We may be subject to extensive environmental, health and safety, and otherlaws and regulations in multiple jurisdic

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safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents.

We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, 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 physician-administered drugs. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare & Medicaid Services, or CMS, has issued and will continue to issue regulations to implement the new law which will affect Medicare, Medicaid and other third-party payors. Medicare, which is the single largest third-party payment program and which is administered by CMS, covers prescription drugs in one of two ways. Medicare part B covers outpatient prescription drugs that are administered by physicians and Medicare part D covers other outpatient prescription drugs, but through private insurers. Medicaid, a health insurance program for the poor, is funded jointly by CMS and the states, but is administered by the states; states are authorized to cover outpatient prescription drugs, but that coverage is subject to caps and to substantial rebates. The CMS also has the authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the Medicare Modernization Act and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, or the 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 health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from

15.1% of average manufacturer price, or AMP, to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100.0% of AMP. The Affordable Care Act and subsequent legislation also narrowed the definition of AMP. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a

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In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, in August 2011, the President of the U.S. signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If we ever obtain regulatory approval and commercialization of aramchol, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be 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 aramchol may be.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

It will be difficult for us to profitably sell aramchol if reimbursement for the product is limited by government authorities and third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of aramchol will depend on the reimbursement policies of government authorities and third-party payors. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, 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 aramchol 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 is:

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

Obtaining coverage and reimbursement approval for a product 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 products 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 our future products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not

It will be difficult for us to profitably sell aramchol if reimbursement for the product is limited by government authoriti

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available, or is available only to limited levels, we may not be able to commercialize our product candidate, or any future product candidates, profitably, or at all, even if approved.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We are subject to federal anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences to us.

There are extensive U.S. federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute, which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes the U.S. Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts. In addition, the Affordable Care Act requires drug manufacturers to report to the government any payments to physicians for consulting services and the like.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both, and debarment. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use by physicians of any of our products, once commercialized, may dissuade physicians from either purchasing or using them, and could have a material adverse effect on our ability to commercialize those products.

If we or our manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.

Before an NDA is approved, or before we begin the commercial manufacture of aramchol, contract manufacturers must obtain regulatory approval of their manufacturing facilities, processes and quality systems. In addition,

pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections in a cost effective manner.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with requirements that the FDA or foreign regulators establish. We do not intend to engage in the manufacture of our products other than for preclinical and clinical studies, but we or our materials suppliers may face manufacturing or quality control

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problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA s or foreign regulators requirements necessary to continue manufacturing our product candidate. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the U.S. Drug Enforcement Agency, or DEA, and corresponding foreign regulators to ensure strict compliance with requirements and other governmental regulations and corresponding foreign standards. Any failure to comply with DEA, FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop and market our product candidate and any future product candidates.

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.

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

There are a number of products in development for NASH in patients who also suffer from obesity and insulin resistance, most of which are being developed by pharmaceutical companies that are far larger, with significantly greater resources and more experienced than we are. Further, our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large, fully-integrated 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 aramchol or other product candidates. 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 aramchol. Key competitive factors affecting the commercial success of aramchol and any other product candidates that we develop 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. Accordingly, our competitors may be more successful than us 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 aramchol or any other product candidates 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 aramchol, or any other product candidate that we develop, non-competitive or obsolete. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may never be profitable.

Our competitors currently include companies with marketed products and/or an advanced research and development pipeline. The majority of competitors in the liver disease therapeutic field include Intercept Pharmaceuticals Inc., Genfit S.A., Gilead Sciences, Inc., Raptor Pharmaceutical Corp. and Novo Nordisk. See also Business Competition. Moreover, several companies have reported the commencement of research projects related to NASH, including those mentioned in the preceding sentence. However, we are not aware if such projects are ongoing or have been completed

and, to the best of our knowledge, there is no approved drug currently on the market which is similar to aramchol, nor are we aware of any product candidate targeting NASH similar to aramchol with respect to chemical profile and mechanism of action.

Our market is subject to intense competition. If we are unable to compete effectively, aramchol or any other product

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

Our products and product candidates could cause adverse events. These adverse events may not be observed in clinical trials, but may nonetheless occur in the future. If any of these adverse events occur, they may render our product candidates ineffective or harmful in some patients, and our sales would suffer, materially adversely affecting our business, financial conditions and results of operations.

In addition, potential adverse events caused by our product candidates, or products, could lead to product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

Although our clinical data indicates that aramchol is safe and well-tolerated at doses up to 900 mg, administered once-daily for up to four days and at doses up to 300 mg administered once-daily for up to three months, there were incidences of adverse events in three completed and fully analyzed clinical trials with respect to a total of 102 patients.

In our Phase Ia clinical trial with 16 healthy volunteers, elevated systolic blood pressure was the only adverse event reported by three patients. Adverse events that were reported by two or less patients included lymphophenia, tachycardia, asthenia, decreased diastolic blood pressure, headache, pharyngeal edema, increased alanine aminotransferase, increased gamma glutamyl transferase and proteinuria. Nausea and orthostatic hypotension was reported by one subject in each of the aramchol and placebo groups. The adverse events were considered non-severe and possibly drug-related.

In our Phase Ib placebo-controlled clinical trial with 25 healthy and mildly overweight male volunteers, the placebo group had a higher incidence of overall adverse events than the aramchol-treated groups, as well as a higher incidence of drug-related adverse events than the aramchol-treated groups. Adverse events reported by more than two patients included elevated systolic blood pressure, headache (reported by a similar proportion of subjects in the aramchol-treated and placebo groups), orthostatic hypotension (reported by a larger proportion of subjects in the placebo group), tachypnea, tachycardia, increased alanine aminotransferase (reported by a larger proportion of subjects in the placebo group), hematuria (reported by a similar proportion of subjects in the aramchol-treated and placebo groups) and decreased diastolic blood pressure.

Adverse events that were reported only once in any treatment group but considered related to aramchol included increased blood pressure and dizziness. Eosinophilia and increased aspartate aminotransferase were reported only once and only in the placebo group.

In a phase IIa placebo-controlled trial with 60 patients with steatosis due to NAFLD or NASH, the placebo group had a higher incidence of overall adverse events than any aramchol-treated group, as well as a higher incidence of drug-related adverse events than any aramchol-treated group. Incidents reported in more

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

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than two patients included abdominal pain, upper abdominal pain and respiratory tract infection. Back pain, constipation and asthenia were reported only in the placebo group. In this trial, there were no adverse events in the aramchol-treated groups that were considered to be drug-related. Only one serious adverse event was reported during the trial, acute appendicitis, by a subject in the placebo group.

If we are unable to obtain adequate insurance to protect our business and property against damage, our financial condition could be adversely affected in the event of uninsured or inadequately insured loss or damage. Our ability to effectively recruit and retain qualified officers and directors could also be adversely affected if we experience difficulty in obtaining adequate directors and officers liability insurance.

We may not be able to obtain insurance policies on terms affordable to us that would adequately insure our business and property against damage, loss or claims by third parties. To the extent our business or property suffers any damages, losses or claims by third parties, which are not covered, or adequately covered, by insurance, our financial condition may be materially adversely affected.

We may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage the Company.

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

We have obtained liability insurance coverage for our clinical trials with a $5,000,000 annual aggregate coverage limit. 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 aramchol, 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.

We manage our business through a small number of senior executive officers. We depend on them even more than similarly-situated companies.

Our future growth and success depends on our ability to recruit, retain, manage and motivate our senior executive officers. The loss of the services of our Chief Executive Officer, Chief Medical Officer, Dr. Maureen Graham and Dr. Antony Appleyard 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.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified senior executive officers with scientific and technical experience. In particular, the loss of one or more of our senior executive officers 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.

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Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements for publicly traded companies.

As a public company, we will operate in an increasingly challenging regulatory environment which requires us to comply with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the related rules and regulations of the SEC and securities exchanges, expanded disclosures, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, until the date we are no longer an emerging growth company as defined in the JOBS Act, because we are taking advantage of the exemptions contained in the JOBS Act. We will remain an emerging growth company until, subject to certain conditions, 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 $700.0 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall.

To build our finance infrastructure, we will need to hire additional accounting personnel and improve our accounting systems, disclosure policies, procedures and controls. If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Capital Market or other adverse consequences that would materially harm our business. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

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

We may experience rapid and substantial growth in order to achieve our operating plans, which will place a strain on our human and capital resources. Successful implementation of our business plan will require management of growth, which will result in an increase in the level of responsibility for management personnel. We currently have a minimum number of employees and in order to continue the development and the commercialization of our products, we will need to substantially increase our operations, including expanding our employee base of managerial, operational and financial personnel. We currently intend to establish our infrastructure in the United States and

therefore we may require additional funds. 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:

- manage our clinical trials and the regulatory process effectively;
- develop our administrative, accounting and management information systems and controls;
- hire and train additional qualified personnel; and

We will need to significantly increase the size of our organization, and we mayexperience difficulties in managing gr

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integrate current and additional management, administrative, financial and sales and marketing personnel. If we are unable to establish, scale-up and implement improvements to our control systems in an efficient or timely manner, or if we encounter deficiencies in existing systems and controls, investors may choose not to invest in us, which could cause our share price to decline and negatively impact our ability to successfully commercialize our product candidate and future product candidates.

Failure to attract and retain sufficient numbers of talented employees will further strain our human resources and could impede our growth or result in ineffective growth. If we are unable to manage our growth effectively, our losses could materially increase and it will have a material adverse effect on our business, results of operations and financial condition.

Our business may be affected by macroeconomic conditions.

A deterioration in global economic conditions and uncertainties may have an adverse effect on our business. For instance, interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments, if any, and our ability to liquidate such investments in order to fund our operations. Interest rates and the ability to access credit markets could also adversely affect the ability of patients and distributors to purchase, pay for and effectively distribute our products.

Recent disruptions in the financial markets and economic conditions could affect our ability to raise capital and could disrupt or delay the performance of our third-party contractors and suppliers.

In past years, the U.S. and global economies have taken a dramatic downturn as the result of the deterioration in the credit markets and related financial crisis as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have recently taken actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by these governments are not successful, the continued economic decline may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all. In addition, we rely and intend to rely on third-parties, including our clinical research organizations, third-party manufacturers and second source suppliers, and certain other important vendors and consultants. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to satisfy their contractual commitments to us, our business could be severely adversely affected.

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 the production of aramchol or its active pharmaceutical ingredients, or APIs. We still have not, and may never, develop facilities for the manufacture of product candidates or products for clinical trials or commercial purposes. We rely, and for the foreseeable future, will continue to rely, on third-party manufacturers to produce bulk drug products required for our clinical trials. We plan to initially rely upon

contract manufacturers and, potentially, collaboration partners, to manufacture commercial quantities of our product candidates, if and when approved for marketing by the applicable regulatory authorities. Our contract manufacturers have not completed process validation for the drug substance manufacturing process. If our contract manufacturers and their facilities, as applicable, are not approved by the FDA, or other applicable regulatory authorities, our commercial supply of the drug substance will be significantly delayed and may result in significant additional costs. We purchase finished aramchol from a third-party under a clinical supply agreement. If we need to identify an additional finished product 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,

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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 aramchol would be interrupted, resulting in delays and additional costs.

We intend to rely primarily on third parties to market and sell aramchol.

We have no sales or distribution capabilities. To the extent we rely on third parties to commercialize aramchol, if marketing approval is obtained, we may receive less revenue than if we commercialize aramchol 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 aramchol, particularly for broader patient populations, our ability to generate revenue will be limited.

Although we may ultimately develop a marketing and sales force with technical expertise and supporting distribution capabilities in the longer term, we do not currently intend to do so and as such, we will be unable to market our product candidate directly in the near future. To promote any of our potential products through third parties, we will have to locate acceptable third parties for these functions and enter into agreements with them on acceptable terms, and we may not be able to do so. Any third-party arrangements we are able to enter into may result in lower revenues than we could achieve by directly marketing and selling our potential products. In addition, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted in most cases at this time. As a result, we might not be able to market and sell our products in the United States or overseas, which would have a material adverse effect on us.

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 intend to seek collaboration arrangements with pharmaceutical or biotechnology companies for the development and commercialization of our current and potential future product candidates. 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. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

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

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

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

We 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 most of the operations of our clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties

Any collaboration arrangements that we may enter into in the future may notbe successful, which could adversely a

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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 aramchol 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

The failure to obtain or maintain patents, licensing agreements and other intellectual property could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. Therefore, the degree of future protection for our proprietary rights in our core technologies and any product candidates or products that might be developed using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

while the patents we own have been issued, pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;

we may be subject to interference or reexamination proceedings;

we may be subject to opposition proceedings in foreign countries;

any patents that are issued may not provide meaningful protection for any significant period of time, if at all;

we may not be able to develop additional proprietary technologies that are patentable;

other companies may challenge and invalidate patents licensed or issued to us or our customers;

other companies may independently develop similar or alternative technologies, or duplicate our technologies;

other companies may design around technologies we have licensed or developed; and

enforcement of patents is complex, uncertain and expensive, and our patents may be found invalid or enforceable.

We cannot be certain that patents will be issued as a result of any of our pending applications, and we cannot be certain that any of our issued patents, whether issued pursuant to our pending applications or licensed from third parties, will give us adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions. If any of our composition of matter patents, or pending applications, was subject to a successful challenge or failed to issue, our business and competitive advantage could be significantly affected. Our current patents will expire or they may otherwise cease to provide meaningful competitive advantage, and we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage or avoid adverse effects on our business.

The composition of matter patents pertaining to aramchol will expire on March 25, 2019 worldwide outside of Israel and on April 8, 2018 in Israel. We do not expect that we will be able to submit an NDA seeking approval of aramchol prior to the composition of matter patents expiration date. However, because aramchol may be a new chemical entity, or NCE, following approval of an NDA, if we are the first applicant to obtain NDA approval, we may be entitled to five years of data and market exclusivity in the United States with respect to such NCE. Analogous data and market exclusivity provisions, of varying duration, may be available in Europe and other foreign jurisdictions. The Company

also has rights under its pharmaceutical use issued patents with respect to aramchol, which provide patent exclusivity within the Company s field of

The failure to obtain or maintain patents, licensing agreements and otherintellectual property could impact our abilit

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activity until the last of such patents expires in 2030. While the Company believes that it may be able to protect its exclusivity in its field of activity through such use patent portfolio and such period of exclusivity, the lack of composition of matter patent protection may diminish the Company s ability to maintain a proprietary position for its intended uses of aramchol. Moreover, the Company cannot be certain that it will be the first applicant to obtain an FDA approval for any indication of aramchol and it cannot be certain that it will be entitled to NCE exclusivity. Such diminution of its proprietary position could have a material adverse effect on our business, results of operation and financial condition.

Others may obtain issued patents that could prevent us from commercializing our product candidates or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We also require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

We cannot predict the scope and extent of patent protection for aramchol because the patent positions of pharmaceutical products are complex and uncertain.

Any patents issued will not ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
if we are not awarded patents or if issued patents expire or are declared invalid or not infringed, there may be no protections against competitors making generic equivalents;
there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
there may be other patents or pending patent applications existing in the patent landscape for aramchol that will affect our freedom to operate;
if our patents are challenged, a court could determine that they are not valid or enforceable;
a court could determine that a competitor s technology or product does not infringe our patents;
our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
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 we expect aramchol will be manufactured and used in a number of foreign countries.

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 we expect aramchol will be manufactured and used in a number of foreign countries.

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 our other intellectual property rights. For example, several foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In

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addition, some 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.

Although most jurisdictions in which the Company has applied for, intends to apply for, or has been issued patents have patent protection laws similar to those of the United States, some of them do not. For example, the Company expects to do business in South America, Eurasia, China and Indochina in the future and the countries in these regions may not provide the same or similar protection as that provided in the United States. Additionally, due to uncertainty in patent protection law, the Company has not filed applications in many countries where significant markets exist, including South American countries, Eurasian countries, African countries and Taiwan.

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 be unable to protect the intellectual property rights of the third parties from whom we may license certain of our intellectual property or with whom we have entered into other strategic relationships, which could have a material adverse effect on our business, results of operations and financial condition.

Certain of our intellectual property rights may be licensed from third parties, including universities and/or strategic partners. Such third parties may determine not to or fail to protect the intellectual property rights that we license from them and we may be unable to defend such intellectual property rights on our own or we may have to undertake costly litigation to defend the intellectual property rights of such third parties. There can be no assurances that we will continue to have proprietary rights to any of the intellectual property that we license from such third parties or otherwise have the right to use through similar strategic relationships. Any loss or limitations on use with respect to such intellectual property licensed from third parties or otherwise obtained from third parties with whom we have entered into strategic relationships could have a material adverse effect on our business, results of operations and financial condition.

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 product candidates or products unless we obtained a license under the applicable patents, or until the patents expire. In addition to litigation proceedings which may be filed against us, 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.

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We may be unable to adequately prevent disclosure and unauthorized use of trade secrets and other proprietary information by third parties.

Our ability to obtain and maintain patent protection and trade secret protection for our intellectual property and proprietary technologies, our products and their uses is important to our commercial success. We rely on a combination of patent, copyright, trademark and trade secret laws, non-disclosure and confidentiality agreements, licenses, assignment of inventions agreements and other restrictions on disclosure and use to protect our intellectual property rights.

We also 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 product candidates or products or cause additional material adverse effects upon our competitive business position.

We cannot be certain that the steps that we have taken will prevent the misappropriation or other violation of our confidential information and other intellectual property, particularly in foreign countries in which laws may not protect our proprietary rights as fully as in the United States and other developed economies. Moreover, if we lose any key personnel, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by those former employees. If we are unable to maintain the security of our proprietary technology, this could materially adversely affect our competitive advantage, business and results of operations.

Under applicable U.S. and Israeli law, 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, which in turn could impact our future profitability.

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, Chapter 8 to the Israeli Patents Law, 5727-1967, or the Patents Law, deals with inventions made in the course of an employee s service and during his or her term of employment, whether or not the invention is patentable, or service inventions. Section 134 of the Patents Law, sets forth that if there is no agreement which explicitly determines whether the employee is entitled to compensation for the service inventions and the extent and terms of such compensation, such determination will be made by the Compensation and Rewards Committee, a statutory committee of the Israeli Patents Office. The Israeli Supreme Court ruled in 2012 that an employee who contributes to a service invention during his or her 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 assigned all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes the employee s right for

Under applicable U.S. and Israeli law, we may not be able to enforcecovenants not to compete and therefore may b

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royalties and compensation in connection with service inventions does not rule out the right of the employee to claim their right for royalties. Following such ruling, the Israeli Supreme Court remanded the proceedings to the District Court for further discussion and therefore the ultimate outcome has yet to be resolved. As a result, it is unclear if, and to what extent, our research and development 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.

We may be required 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 and who claim that their rights are infringed by aramchol or any of our 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.

A third-party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that such court will decide that we are infringing the third-party s patents and will order us to stop the activities claimed by the patents, redesign our products or processes to avoid infringement or obtain licenses, which may not be available on commercially reasonable terms. In addition, there is a risk that a court will order us to pay the other party damages for infringement.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our product candidates, technologies or other matters.

In addition, our patents and patent applications 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 patents 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 patent law could diminish the value of patents 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 particular, 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, and could do so again in the future, 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 applicable courts and legislatures in the countries in which we may pursue patent protection, including those of the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office, or the

USPTO, the laws and regulations governing patents and the interpretations of such laws 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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our proc

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

Risks Related to this Offering and Ownership of Our Ordinary Shares

The market price of our ordinary shares may be highly volatile, you may not be able to resell your Shares at or above the initial public offering price and you may sustain a complete loss of your investment.

Prior to this offering, there has not been a public market for our ordinary shares. Although the Shares have been approved for listing on the Nasdaq Capital Market, an active trading market for our ordinary shares may never develop or may not be sustained if one develops. If an active trading market for our ordinary shares does not develop following this offering, you may not be able to sell your Shares quickly or at the market price. The initial public offering price for the Shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market.

The trading price of our ordinary shares is likely to be volatile. The following factors, some of which are beyond our control, in addition to other risk factors described in this section, may have a significant impact on the market price of our ordinary shares:

inability to obtain the approvals necessary to commence further clinical trials;
unsatisfactory results of clinical trials;
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;
announcements of therapeutic innovations or new products by us or our competitors;
adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
changes or developments in laws or regulations applicable to aramchol;
any adverse changes to our relationship with manufacturers or suppliers;
any product liability actions or intellectual property infringement actions in which we may become involved;
announcements concerning our competitors or the pharmaceutical industry in general;
achievement of expected product sales and profitability or our failure to meet expectations;
our commencement of, or involvement in, litigation;
any major changes in our board of directors, or our Board, management or other key personnel;
legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;

announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;

expiration or terminations of licenses, research contracts or other collaboration agreements;

public concern as to the safety of drugs we, our licensees or others develop;

success of research and development projects;

The market price of our ordinary shares may be highly volatile, you may notbe able to resell your Shares at or abov

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variations in our and our competitors results of operations;
changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
developments by our licensees, if any; and
future issuances of ordinary shares or other securities.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and result in substantial losses by our investors.

In addition, the stock market in general, and the Nasdaq Capital Market and the market for biotechnology companies 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. Price volatility of our ordinary shares might be worse if the trading volume of our ordinary shares is low. Following periods of market volatility, shareholders may institute securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. Future sales of our ordinary shares could also reduce the market price of such stock.

Moreover, the liquidity of our ordinary shares will be limited, not only in terms of the number of shares that can be bought and sold at a given price, but by delays in the timing of transactions and reduction in security analysts and the media s coverage of us, if any. These factors may result in lower prices for our ordinary shares than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our ordinary shares. In addition, without a large float, our ordinary shares are less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our ordinary shares may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our ordinary shares. Trading of a relatively small volume of our ordinary shares may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our ordinary shares will trade in the future.

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

Companies have experienced volatility and other negative fluctuations 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 principal shareholders, Chief Executive Officer and directors currently own approximately 70.17% of our outstanding ordinary shares and will own approximately 52.76% 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 Chief Executive Officer, directors and shareholders who own more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own approximately 52.76% of our ordinary shares upon the closing of this offering (assuming no exercise of the underwriters over-allotment option and no

exercise of outstanding options). 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. 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.

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If you purchase Shares in this offering, you will incur immediate and substantial dilution in the book value of your Shares.

The initial public offering price is substantially higher than the net tangible book value per share of our ordinary shares. Investors purchasing 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 Shares in this offering will incur immediate dilution of $10.25 per Share, based on the initial public offering price of $13.50 per Share, and our pro forma, as adjusted net tangible book value as of December 31, 2013. In addition, as of that date, options and warrants to purchase 1,499,553 of our ordinary shares at a weighted average exercise price of $1.13 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. Substantially all 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 six months from the date hereof. In addition, the holders of substantially all of our outstanding ordinary shares and options have agreed, in accordance with the terms of the Tax Pre-Ruling, not to sell or dispose of our ordinary shares for a period of two years following the consummation of the Reorganization, subject to certain exceptions. Substantially all of our outstanding shares will become eligible for unrestricted sale upon expiration of such lockup periods, as described in the section of this prospectus entitled Underwriting and Taxation Israeli Tax Considerations Pre-Ruling Regarding a Reorganization of Our Corporate Structure. 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.

All of our Shares sold in this offering that are not subject to lock-up agreements will be freely tradable without restrictions or further registration under the Securities Act, except for any Shares purchased by our affiliates, as such term is defined in Rule 144 under the Securities Act, which shares will be eligible for resale subject to the volume and manner of sale limitations of Rule 144. See Shares Eligible for Future Sale for a discussion of the ordinary shares that may be sold into the public market in the future.

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, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt 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.

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 from this offering, 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

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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, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders.

Our U.S. shareholders may suffer adverse tax consequences if we were to be characterized as a passive foreign investment company, or PFIC.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. There can be no assurance that we will not be classified as a PFIC in any year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder, as defined in Taxation U.S. Federal Income Tax Consequences, owns ordinary shares, such U.S. Holder could face adverse U.S. federal income tax consequences. For example, such U.S. Holder could be liable to additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition of our shares, whether or not we continue to be characterized as a PFIC. One way in which certain of the adverse consequences of PFIC status can be mitigated is for a U.S. Holder to make an election to treat us as a qualified electing fund, or QEF. A shareholder making the QEF election is required for each taxable year to include in income a pro rata share of the ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election. See Taxation U.S. Federal Income Tax Consequences.

If we are unable to satisfy the requirements of Section 404 as they apply to a foreign private issuer and emerging growth company that is listing on a U.S. exchange for the first time, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our share price may suffer.

We will become subject to the requirements of the Sarbanes-Oxley Act when our ordinary shares are listed on the Nasdaq Capital Market. Section 404 requires companies subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its subsidiaries internal controls over financial reporting. To comply with this statute, we will be required to document and test our internal control procedures and our management will be required to assess and issue a report concerning our internal controls over financial reporting. Pursuant to the JOBS Act, we will be classified as an emerging growth company. Under the JOBS Act, emerging growth companies are exempt from certain reporting requirements, including the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on management s assessment of our internal controls over financial reporting during a five year transition period. We will need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for our report. However, the continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, as our business continues to grow both domestically and internationally, our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of its testing, our management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely

manner to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and the market price of our securities may suffer. Nevertheless, as a foreign private issuer that is an emerging growth company, we will not be required to comply with the auditor attestation requirements of Section 404 for up to five fiscal years after the date of this offering. See Management s Discussion and Analysis of Financial Condition and Results of Operations Jumpstart Our Business Startups Act of 2012 for more detail regarding our status as an emerging growth company.

If we are unable to satisfy the requirements of Section 404 as they apply to aforeign private issuer and emerging gr

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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 be negatively impacted.

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 negatively impact our share price or trading volume.

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, as amended, or the Companies Law, imposes certain restrictions on our ability to declare and pay dividends. See Description of Share Capital Dividend and Dividend Policy for additional information.

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

Following this offering, we will become 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 Capital Market may also impose various additional requirements on public companies. As a result, we will incur additional legal, accounting and other expenses that we did not incur as a privately-held company, particularly after we are no longer an emerging growth company as defined in the JOBS Act. In the period following this offering, we estimate that these expenses will be at least several hundred thousand dollars annually. Further, the need to establish the corporate infrastructure demanded of a public company may divert management s attention from implementing our development plans. We have made changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations and applicable law. 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:

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;

The recently enacted JOBS Act will allow us to postpone the date by which wemust comply with some of the laws a

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the say on pay provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, requiring a non-binding shareholder vote to approve compensation of certain executive officers, and the Dodd-Frank Act s say on golden parachute provisions requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our Chief Executive Officer;

any rules that may be adopted by the Public Company Accounting Oversight Board, or the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor s report on the financial statements; and

our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

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 become more volatile and decline.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq Capital Market 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 Capital 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, quorum requirements and approval of compensation of officers. In addition, we may follow our home country law instead of the Listing Rules of the Nasdaq Capital 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 U.S. company listed on the Nasdaq Capital Market may provide less protection to you than what is accorded to investors under the Listing Rules of the Nasdaq Capital Market applicable to domestic U.S. issuers. See Management Nasdaq Capital Market Listing Rules and Home Country Practices.

In addition, as a foreign private issuer, we will be exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements and certain individual executive compensation information, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated 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. Notwithstanding, although we will not be 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, we intend to do so.

Because our ordinary shares may be a penny stock, it may be more difficult for investors to sell their ordinary shares, and the market price of our ordinary shares may be adversely affected.

Our ordinary shares may be a penny stock if, among other things, the stock price is below $5.00 per share, it is not listed on a national securities exchange or we have not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the

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purchaser, and obtain the purchaser s written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their ordinary shares. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stocks and the market price of our ordinary shares may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to resell their ordinary shares publicly at times and prices that they feel are appropriate and the market price of our ordinary shares may be adversely affected.

The Shares are approved for listing on the Nasdaq Capital Market. As such, we must meet the Nasdaq Capital Market s continued listing requirements and other Nasdaq rules, or we may risk delisting. Delisting could negatively affect the price of our ordinary shares, which could make it more difficult for us to sell securities in a financing and for you to sell your ordinary shares.

The Shares are approved for listing on the Nasdaq Capital Market. As such, we are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed ordinary shares of $1.00 per share. If we do not meet these continued listing requirements, our ordinary shares could be delisted. Delisting of our ordinary shares from the Nasdaq Capital Market would cause us to pursue eligibility for trading on other markets or exchanges, or on the pink sheets. In such case, our shareholders ability to trade, or obtain quotations of the market value of, our ordinary shares would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our ordinary shares, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the Over-The-Counter Markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our ordinary shares, reduce security analysts coverage of us and diminish investor, supplier and employee confidence. In addition, as a consequence of any such delisting, our share price could be negatively affected and our shareholders would likely find it more difficult to sell, or to obtain accurate quotations as to the prices of, our ordinary shares.

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. In December 2008 and January 2009 there was an escalation in violence among Israel, Hamas, the Palestinian Authority and other groups, as well as extensive hostilities along Israel s border with the Gaza Strip, which resulted in missiles being fired from the Gaza Strip into Southern Israel. Similar hostilities accompanied by missiles being fired from the Gaza Strip into Southern Israel, as well at areas more centrally located near Tel Aviv and at areas surrounding Jerusalem, occurred during November 2012. 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. Since February 2011, Egypt has experienced

Our headquarters and other significant operations are located in Israel and,therefore, our results may be adversely

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political turbulence and an increase in terrorist activity in the Sinai Peninsula following the resignation of Hosni Mubarak as president. This included protests throughout Egypt, and the appointment of a military regime in his stead, followed by the elections to parliament which brought groups affiliated with the Muslim Brotherhood (which had been previously outlawed by Egypt), and the subsequent overthrow of this elected government by a military regime instead. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. Intervention may be contemplated by outside parties in order to prevent further chemical weapon use. This instability and any intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. 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 Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty until they reach the age of 40 (or older, for reservists who are officers or who have certain occupations) and, in the event of a military conflict, 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 military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of our employees or the employees of our Israeli business partners. Such disruption could materially adversely affect our business, financial condition and results of operations.

Exchange rate fluctuations between the U.S. dollar, Euro and the New Israeli Shekel currencies may negatively affect our earnings.

Our functional currency is the U.S. dollar. We incur expenses in U.S. dollars, Euros and New Israeli Shekels, or NIS. As a result, we are exposed to the risks that the Euro and the NIS may appreciate relative to the U.S. dollar, or, if either the Euro and the NIS devalue relative to the U.S. dollar, that the inflation rate in the EU and in Israel may exceed such rate of devaluation of the Euro and the NIS, or that the timing of such devaluation may lag behind inflation in the EU and in Israel. In any such event, the U.S. dollar cost of our operations in the EU and in Israel would increase and our U.S. dollar-denominated results of operations would be adversely affected. The average exchange rate for the year ended December 31, 2013 was

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$1.00 = Euro 1.3292 and $1.00 = NIS 3.61. We cannot predict any future trends in the rate of inflation in the EU and in Israel or the rate of devaluation, if any, of either the Euro or the NIS against the U.S. dollar. As of the date hereof, neither the inflation rate in the EU nor in Israel has exceeded the rate of devaluation of the Euro or the NIS, respectively, during the calendar years 2011, 2012 or 2013.

The Tax Pre-Ruling imposes restrictions and limitations that may adversely affect our ability to raise funds by selling our ordinary shares and our ability to commercialize our product candidate.

The Tax Pre-Ruling we obtained from the Israeli Tax Authority in connection with the Reorganization includes certain restrictions and limitations. Under the Tax Pre-Ruling, during the two year period following the consummation of the Reorganization, or the Restriction Period, we may not sell or otherwise dispose of our intellectual property, other than in the ordinary course of business, which may prevent us from completing collaboration arrangements with pharmaceutical or biotechnology companies necessary for the commercialization of our product candidate.

Pursuant to the Tax Pre-Ruling, at any time following this offering and until the end of the Restriction Period, we may not issue more than 49% of our share capital in a public or private offering, including the Shares to be sold in this offering. Such restrictions and limitations may limit our ability to raise funds by selling and issuing our ordinary shares, which in turn could delay the development and commercialization of our product candidate or could force us to cease our operations.

In addition, pursuant to the Tax Pre-Ruling, our shareholders and optionholders as of immediately after the consummation of the Reorganization may not sell or otherwise transfer or dispose of more than 10% of their respective shares and options, subject to a certain exemptions. Substantially all of such shareholders and option holders agreed, in accordance with the terms of the Tax Pre-Ruling, not to sell or dispose of our ordinary shares for a period of two years following the consummation of the Reorganization.

If during the Restriction Period, we or our shareholders or optionholders who held rights immediately after the consummation of the Reorganization, or the Rights Holders, violate one or more of the restrictions described under Taxation Israeli Tax Considerations Pre-Ruling Regarding a Reorganization of Our Corporate Structure below, or a Violation, the transfer of shares and assets in connection with the Reorganization will become subject to taxation based on the greater of the transferred assets fair market value on the day of such Violation or taxes that, but for the Tax Pre-Ruling, would be payable in connection with the transfer of such assets and shares plus Israeli consumer price index linkage differentials and interest from the day of the actual transfer of such assets and shares until the day of payment of such taxes, unless the Israeli Tax Authority is satisfied that such Violation was a result of special circumstances beyond our control.

Provisions of Israeli law and our Articles 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.

Provisions of Israeli law and our Articles may delay, prevent or otherwiseimpede a merger with, or an acquisition of,

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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 Articles, which will be in effect immediately prior to the consummation of this offering, also contain provisions that could delay or prevent changes in control or changes in our management without the consent of our Board. These provisions will include the following:

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

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

Provisions of the Companies Law and anti-takeover provisions in our Articles could make it difficult for our shareholders to replace or remove our current Board and could have the effect of discouraging, delaying or preventing a merger or acquisition, which could adversely affect the market price of our ordinary shares.

Under the Companies Law, as amended, a merger is generally required to be approved by the shareholders and board of directors of each of the merging companies. Unless an Israeli court determines differently, a merger will not be approved if it is objected to by shareholders holding a majority of the voting rights participating and voting at the meeting, after excluding the shares held by the other party to the merger, by any person who holds 25% or more of the other party to the merger or by anyone on their behalf, including by the relatives of or corporations controlled by these persons. In addition, upon the request of a creditor of either party to the proposed merger, an Israeli 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. Further, a merger generally may not be completed until the passage of certain time periods. In addition, subject to certain exceptions, an acquisition of shares in a public company must be made by means of a tender offer to the extent that as a result of such acquisition the acquirer will hold 25% or more of the voting rights in the company if there is no other holder of 25% or more of the company s voting rights, or hold 45% or more of the voting rights in the company if there is no other holder of 45% or more of the company s voting rights. In addition, Israeli tax law treats some acquisitions, including stock-for-stock swaps between an Israeli company and a foreign company, less favorably than U.S. tax law. Israeli tax law may, for instance, subject a shareholder who exchanges ordinary shares for shares in a non-Israeli corporation to immediate taxation.

Certain provisions of our Articles may have the effect of rendering more difficult or discouraging an acquisition of the Company deemed undesirable by the Board. Those provisions include:

limiting the ability of our shareholders to convene general meetings of the Company;

controlling procedures for the conduct of shareholder and our Board meetings, including quorum and voting requirements; and

the election and removal of directors.

Moreover, the classification of our Board into three classes with terms of approximately three years each, which was approved by shareholders of the Company, the requirement of affirmative vote of at least 75% of the voting rights represented personally or by proxy and voting thereon at a general meeting in order to amend or replace our Articles

and the requirement under the Companies Law to have at least two external directors who cannot readily be removed from office, together with the other provisions of the Articles and Israeli law, could deter or delay potential future merger, acquisition, tender or takeover offers, proxy contests or changes in control or management of the Company, some of which could be deemed by certain shareholders to be in their best interests and which could affect the price some investors are willing to pay for our ordinary shares.

Provisions of the Companies Law and anti-takeover provisions in our Articles could make it difficult for our shareholders

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It may be difficult to enforce a judgment of a United States court against us, our officers, 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, directors and these experts.

We were and continue to be organized in Israel. Substantially all 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 rights, liabilities and responsibilities as a shareholder will be governed by Israeli law and differ in some material respects from those under U.S. law.

Because we are an Israeli company, the rights and responsibilities of our shareholders are governed by the Articles and Israeli law. These rights, liabilities and responsibilities differ in some material respects from the rights, liabilities and responsibilities of shareholders in a U.S. corporation. In particular, a shareholder of an Israeli company has a duty to act in good faith towards the company and other shareholders and to refrain from abusing his, her or its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters. Israeli law provides that these duties are applicable to shareholder votes on, among other things, amendments to a company s articles of association, increases in a company s authorized share capital, mergers and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. Because Israeli corporate law has undergone extensive revisions in recent years, there is little case law available to assist in understanding the implications of these provisions that govern shareholder behavior. See Management Approval of Related Party Transactions under Israeli Law Shareholder Duties for additional information. 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.

Any of the risk factors referred to above could significantly and negatively affect our business, results of operations or financial condition, which may reduce our ability to pay dividends and lower the trading price of our ordinary shares. The risks referred to above are not the only ones that may exist. Additional risks not currently known by us or that we deem immaterial may also impair our business operations. You may lose all

or a part of your investment.

Your rights, liabilities and responsibilities as a shareholder will be governedby Israeli law and differ in some materia

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as believe, expect, intend, plan, may, should or anticipate or their negatives or other variations of the other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below.

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

FDA approval of, or other regulatory action with respect to, aramchol;
the commercial launch and future sales of aramchol or any other future products or product candidates;
our ability to achieve favorable pricing for aramchol;
our expectations regarding the commercial market of NASH in patients who also suffer from obesity and insulin resistance and patients with cholesterol gallstones;
third-party payor reimbursement for aramchol;
our estimates regarding anticipated capital requirements and our needs for additional financing;
patient market size and market adoption of aramchol by physicians and patients;
the timing, cost or other aspects of the commercial launch of aramchol;
the timing and cost of Phase IIb and Phase III trials for aramchol or whether such trials will be conducted at all;
completion and receiving favorable results of Phase IIb and Phase III trials for aramchol;
the development and approval of the use of aramchol for additional indications or in combination therapy; and
our expectations regarding in-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. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date hereof and are expressly qualified in their entirety by the cautionary statements included in this prospectus. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

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USE OF PROCEEDS

We estimate that we will receive approximately $34,385,199 in net proceeds from the sale of 2,837,400 Shares offered by us in this offering (or approximately $39,728,733 if the underwriters exercise their over-allotment option in full), based on the public offering price of $13.50 per Share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering for clinical trials and product development, working capital and general corporate purposes of the Company. In particular, we expect to use the net proceeds as follows: (i) approximately $10.0 million for the initiation and completion of the Phase IIb clinical trial of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance; (ii) in connection with such clinical trial, approximately $5.0 million for establishing and building a research and development infrastructure in the United States, including for the engagement of a new vice president for North America, Phase III clinical trials, pre-commercialization activities, raising disease awareness for NASH, communications with the scientific and medical communities, physicians, third-party payors, future partners and collaborators and investor relations, which we believe may increase our operations and presence within the United States; (iii) approximately $5.0 million for the performance of other studies in connection with our product candidate, including, but not limited to, PK studies and food effect studies, each prior to the consummation of our proposed Phase IIb clinical trial, proof of concept studies with respect to the use of aramchol for the treatment of cholesterol gallstones, the development of salt formulations of aramchol, as opposed to the free acid form, and bioequivalence studies with existing formulations of aramchol; and (iv) for working capital and general corporate purposes of the Company. Pending such usage, we expect to invest the proceeds in short term interest-bearing instruments.

We will require significant additional funds to initiate and complete the approval process of the FDA, EMA or any other applicable regulatory authority. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate. 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.

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

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CAPITALIZATION

The following table sets forth our cash and cash equivalents, total debt and capitalization as of December 31, 2013:

on an actual basis;

on a pro forma basis to give effect to: (i) the Reorganization; (ii) the issuance immediately upon the consummation of this offering of 177,488 ordinary shares upon the exercise of the Warrant, based upon the initial public offering price of $13.50 per Share; and (iii) the issuance of 560,224 ordinary shares for a total consideration of $2.0 million that took place on February 3, 2014;

on a pro forma, as adjusted, basis to give effect to clauses (i), (ii) and (iii) above and the issuance of 2,837,400 Shares in this offering at the initial public offering price of $13.50 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 Use of Proceeds, Selected Consolidated 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.

	As of December 31, 2013 (In thousands, except share and per share data)		
	Actual	Pro Forma (unaudited)	Pro Forma as Adjusted (unaudited)
Cash and cash equivalents	$	$ 2,137	$ 36,768
Convertible notes			
Ordinary shares of NIS 0.01 par value 50,000,000 shares authorized; 7,099,731 shares issued and outstanding, actual; 7,837,443 shares issued and outstanding, pro forma; and 10,674,843 shares issued and outstanding, pro forma as adjusted		22	30
Additional paid-in capital		27,669	62,292
Accumulated deficit		(27,642)	(27,642)
Total shareholders equity (deficiency)		49	34,680
Total capitalization	$	$ 49	$ 34,680

The number of our ordinary shares to be outstanding immediately after this offering is based on 7,659,955 ordinary shares outstanding as of March 12, 2014 and 177,488 ordinary shares issuable upon the exercise of the Warrant, which will be exercised automatically upon the completion of this offering, by way of cashless exercise, at an exercise price per share of $3.57, based upon the initial public offering price of $13.50 per Share. This number excludes 1,298,173 ordinary shares issuable upon the exercise of share options outstanding as of March 12, 2014 under our 2013 Incentive Share Option Plan, or our 2013 Plan, 17,166 ordinary shares issuable upon the exercise of options which will be granted upon the consummation of the offering under our 2013 Plan to Mr. Marth, 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and 784,304 ordinary shares reserved for future grants under our 2013 Plan. These issued options have a weighted average exercise price of $1.13 per share and expire in September 2023, with the exception of the option to purchase 38,637 shares granted to the service provider, which has no expiration date.

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DILUTION

If you invest in the Shares, you will experience immediate and substantial dilution to the extent of the difference between the initial public offering price of the Shares and the pro forma as adjusted net tangible book value (deficit) per share of our ordinary shares immediately after, and giving effect to, the offering. Dilution results from the fact that the per share offering price of the Shares is substantially in excess of the book value per share attributable to the ordinary shares held by existing shareholders.

Our historical net tangible book value (deficit) 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 (deficit) of our ordinary shares as of December 31, 2013 and as of December 31, 2012 was $(0), or $0 per share. On a pro forma basis, giving effect to (i) the Reorganization; (ii) the issuance immediately upon the consummation of this offering of 177,488 ordinary shares upon the exercise of the Warrant, based upon the initial public offering price of $13.50 per Share; and (iii) the issuance of 560,224 ordinary shares for a total consideration of $2.0 million that took place on February 3, 2014, our historical net tangible book value per share was $0.01.

The pro forma as adjusted net tangible book value of our ordinary shares as of December 31, 2013 was $34,680,000, or $3.25 per share. The pro forma as adjusted net tangible book value gives effect to clauses (i), (ii) and (iii) above and the sale of the Shares in this offering at the initial public offering price of $13.50 per Share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted net tangible book value per share after the offering is calculated by dividing the pro forma as adjusted net tangible book value of $34,680,000 by 10,674,843, which is equal to the pro forma as adjusted issued and outstanding ordinary shares of the Company. The difference between the initial public offering price and the pro forma as adjusted net tangible book value (deficit) per share represents an immediate increase in the net tangible book value of $3.24 per share to existing shareholders and immediate dilution of $10.25 per Share to new investors purchasing Shares in this offering.

The following table illustrates this dilution on a per share basis to new investors (in thousands, except per share data):

Initial public offering price per share		$ 13.50
Net tangible book value per share before this offering (as of December 31, 2013)	$	
Decrease in net tangible book value per share attributable to existing investors due to the Reorganization	$ (0.27)	
Increase in net tangible book value per share attributable to existing investors due to the issuance of ordinary shares on February 3, 2014	$ 0.28	
Increase in net tangible book value per share attributable to exercise of the Warrant (as of the date of this offering)	$	
Pro forma net tangible book value per share before this offering (as of December 31, 2013)	$ 0.01	
Increase in net tangible book value per share attributable to new investors in this offering	$ 3.24	
Pro forma as adjusted net tangible book value per share after offering		$ 3.25
Dilution per share to new investors		$ 10.25

If the underwriters over-allotment option to purchase additional Shares from us is exercised in full, and based on the initial public offering price of $13.50 per Share, the pro forma as adjusted net tangible book value per share after this offering would be approximately $3.61 per share, the increase in the pro forma net tangible book value per share attributable to new investors would be approximately $3.60 per Share and the dilution to new investors purchasing Shares in this offering would be approximately $9.89 per Share.

The table below summarizes as of December 31, 2013, on the pro forma as adjusted basis described above, the number of ordinary shares we issued and sold, the total consideration we received and the average

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price per share (1) paid by our existing shareholders and (2) to be paid by new investors purchasing the Shares in this offering at the initial public offering price of $13.50 per Share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing shareholders	7,837,443 (1)	73 %	$ 16,633,181	30 %	$ 2.12
New investors	2,837,400	27 %	38,304,900	70 %	13.50
Total	10,674,843	100 %	$ 54,938,081	100 %	

(1) Consists of 7,659,955 ordinary shares outstanding before the offering and 177,488 ordinary shares issuable upon the exercise of the Warrant.

The number of our ordinary shares to be outstanding immediately after this offering is based on 7,659,955 ordinary shares outstanding as of March 12, 2014 and 177,488 ordinary shares issuable upon the exercise of the Warrant, which will be exercised automatically upon the completion of this offering, by way of cashless exercise, based upon the initial public offering price of $13.50 per Share. This number excludes 1,298,173 ordinary shares issuable upon the exercise of share options outstanding as of March 12, 2014 under our 2013 Plan, 17,166 ordinary shares issuable upon the exercise of options which will be granted upon the consummation of the offering under our 2013 Plan to Mr. Marth, 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and 784,304 ordinary shares reserved for future grants under our 2013 Plan. These issued options have a weighted average exercise price of $1.13 per share and expire in September 2023, with the exception of the option to purchase 38,637 shares granted to the service provider, which has no expiration date.

To the extent that new options are granted under the 2013 Plan or any future adopted equity incentive plan, there will be further dilution to investors purchasing the Shares in this offering.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following table summarizes our financial data (which reflects the financial data of GHI, our predecessor, prior to the Reorganization). We have derived the following statements of operations data for the years ended December 31, 2011, 2012 and 2013, as well as the balance sheet data as of December 31, 2012 and 2013 from our audited consolidated 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 consolidated 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.

	Year ended December 31,		
	2011	2012	2013
	(In thousands, except share and per share data)		
Statements of Operations Data:			
Research and development expenses	$1,326	$2,443	$7,207
General and administrative expenses	151	694	7,355
Capital Loss			10
Operating loss	1,477	3,137	14,572
Financial expenses, net	3	6	2,912
Operating loss post-finance expense & other income, net	1,480	3,143	17,484
Taxes on income	2	6	1
Net loss	$1,482	$3,149	$17,485
Deemed dividend	0	0	0
Loss attributable to holders of ordinary shares	$216.26	$459.51	$2,514.38
Weighted average number of ordinary shares used in computing basic and diluted net loss per share[1]	6,853	6,853	6,954

(1) See Note 2 to our consolidated financial statements for the year ended December 31, 2013, 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.

	As of December 31, 2012	As of December 31, 2013		
	Actual	Actual	Pro forma[1]	Pro forma as adjusted[2]
	(In thousands, except per share data)	(In thousands, except per share data)	(unaudited)	(unaudited)
Balance Sheet Data:				
Cash and cash equivalents	$ 718	$ 137	$ 2,137	$ 36,768
Working capital	219	(1,536)	464	35,095
Total assets	762	166	2,166	36,797

Convertible debt	1,824			
Total liabilities	2,741	2,117	2,117	2,117
Shareholders equity (deficit)	(1,979)	(1,951)	49	34,680

(1) The unaudited pro forma column in the balance sheet data above gives effect to (i) the issuance of 560,224 ordinary shares for a total consideration of $2.0 million that took place on February 3, 2014 and (ii) to the exercise of the Warrant upon the closing of the offering.

(2) The unaudited pro forma as adjusted column in the balance sheet data above gives effect to footnote (1) above as well as the sale of 2,837,400 Shares in this offering at the initial public offering price of $13.50 per Share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, as if the sale had occurred on December 31, 2013.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the Selected Consolidated Financial Data item above and our financial statements and related notes that appear elsewhere in this prospectus. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in the sections titled Risk Factors and Forward-Looking Statements.

Overview

We are an emerging clinical-stage biopharmaceutical company primarily focused on the development and commercialization of novel therapeutics to treat liver diseases and cholesterol gallstones utilizing our proprietary family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Our product candidate, aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, specifically Non-Alcoholic Steato-hepatitis, or NASH, which constitutes a large unmet medical need.

We have successfully completed three clinical trials of aramchol. During the second half of 2014, we intend to begin a multi-center, double-blind, randomized Phase IIb placebo-controlled clinical trial of aramchol in NASH patients who also suffer from obesity and insulin resistance. Our current regulatory path for the development of aramchol for NASH is in accordance with the study design recommended by the MHRA, which has been deemed acceptable or satisfactory, respectively, by two European medical agencies, BfArM and ANSM. These two agencies have confirmed that if successful, this Phase IIb trial may serve as a basis for Phase III pivotal trials of aramchol. If the Phase III trials are completed successfully, we intend to seek regulatory approval of aramchol for the treatment of NASH in the United States and Europe. We currently expect results from the Phase IIb trial to be available in the second half of 2016. During this Phase IIb trial and once 120 patients complete six months of treatment, we intend to conduct an interim analysis of the efficacy and safety of aramchol based on blood markers of inflammation. We currently expect results from such interim analysis to be available in the second half of 2015. We also currently plan to conduct, but provide no assurance that we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of NASH in children, which will be preceded by further preclinical studies and PK studies, and an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones. To date, we have not generated revenue from the sale of any product, and we do not expect to generate any significant revenue unless and until we commercialize aramchol. As of December 31, 2013, the company had a deficit of approximately $27.6 million.

Our financing activities are described below under Liquidity and Capital Resources. Obtaining approval of an NDA, MMA, or other similar application is an extensive, lengthy, expensive and uncertain process, and the FDA, EMA and other regulatory agencies may delay, limit or deny approval of our product.

Financial Overview

Since inception, we have incurred significant losses in connection with our research and development. At December 31, 2012, we had an accumulated deficit of $10.2 million and at December 31, 2013, we had an accumulated deficit of $27.6 million. We will continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further develop our research and development programs.

Since inception, we have not generated any revenue. We have funded our operations primarily through the sale of equity and debt securities in private equity offerings and debt financings in Israel to our affiliates, shareholders and third-party investors. As of December 31, 2013, we had $137,000 in cash and cash equivalents and an accumulated deficit of approximately $27.6 million. Although we provide no assurance, we believe that such existing funds and the proceeds from this offering will be sufficient to continue our business and operations as currently conducted through 2016.

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Costs and Operating Expenses

Our current costs and operating expenses consist of two components: (i) research and development expenses; and (ii) general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of outsourced development expenses, salaries and related personnel expenses and fees paid to external service providers, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. Increases or decreases in research and development expenditures are attributable to the number and/or duration of the preclinical and clinical studies that we conduct.

We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of aramchol for NASH and other indications in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidate in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for our product candidate.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidate, as well as ongoing assessments of the candidate s commercial potential. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for our product candidate in certain indications in order to focus our resources on more promising indications for such product candidate. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

We expect our research and development expenses to increase in the future from current levels as we continue the advancement of our clinical product development and to the extent we in-license new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidate requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Because of the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational roles, including accounting, finance, legal, investor relations, information technology and human resources. Our other significant general and administrative expenses include facilities costs (including, the rental expense for our offices in Tel Aviv, Israel), professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

We expect our general and administrative expenses, such as accounting and legal fees, to increase after we become a public company, and we expect increases in the number of our executive, accounting and administrative personnel due to the anticipated growth of our company.

Financial Expenses, Net

Our financial expense consists of bank fees and loan interest, resulting from the modification of convertible notes. We do not have, and for the last two fiscal years, have not had financial income.

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Critical Accounting Policies and Estimate

We prepare our financial statements in accordance with accounting principles generally accepted in the United States, or GAAP. In doing so, we must make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. In some cases, we could reasonably have used different accounting policies and estimates. Changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. For further significant accounting policies please see Note 2 to our audited consolidated financial statements, beginning on page F-21 of this prospectus. We believe that our accounting policies contained therein are critical in fully understanding and evaluating our financial condition and operating results.

Jumpstart Our Business Startups Act of 2012

We are an emerging growth company within the meaning of the rules under the Securities Act, and we will utilize certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Such exemptions include, but are not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404, (ii) being exempt from adoption of new or revised financial accounting standards until they would apply to private companies, (iii) being exempt from compliance with any new requirements adopted by the PCAOB requiring mandatory audit firm rotation or a supplement to the auditor s report in which the auditor would be required to provide additional information about our audit and our financial statements and (iv) reduced disclosure obligations regarding executive compensation. We could remain an emerging growth company for up to five years from the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1 billion (as such amount is indexed for inflation every five years by the Securities and Exchange Commission, or the SEC, to reflect the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics, setting the threshold to the nearest $1.0 million) or more, (b) the date that we become a large accelerated filer as defined in Rule 12b-2 under the U.S. Securities Exchange Act, which would occur if the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 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.

The JOBS Act also permits us, as an emerging growth company, to take advantage of an extended transition period to comply with certain new or revised accounting standards if such standards apply to companies that are not issuers. We are choosing to opt out of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by issuers. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Stock-Based Compensation and Fair Value of Ordinary Shares

We apply ASC 718-10, Share-Based Payment, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options under the Company's stock plans, based on estimated fair values. ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of the grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated statement of operations. The foregoing estimates of fair value that the Company has made are

highly complex and subjective. The estimates of the fair value of the Company s ordinary shares will not be necessary to estimate the fair value of new awards once the underlying shares begin trading following the consummation of the offering.

We recognize compensation expense for the value of non-employee awards, which have graded vesting, based on the accelerated attribution method over the requisite service period of each award, net of estimated forfeitures. We recognize compensation expense for the value of employee awards that have graded vesting, based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures.

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In determining the fair value of our ordinary shares that was used to value previous equity issuances, we relied upon previous offering valuations while taking into account the clinical development of the Company s product candidate. We believe that the fair value of our ordinary shares has continuously increased since inception as the development of our product candidate has continuously progressed.

The valuations were performed contemporaneously with the offerings of ordinary shares to which such valuations relate. Such valuations were conducted by us and were directly observable in the marketplace. Such valuations were in accordance with the provisions of ASC 820-35 and based on the purchase price paid by new external and independent investors with pharmaceutical or financial expertise, who purchased our convertible notes contemporaneously with or around the time of our equity issuances. Increases in the Company s valuations were based upon the progress in the clinical development of our product candidate, submissions of new families of patent applications for new potential indications and new formulations of our product candidate, an investment round and the anticipated initial public offering of the Company.

We believe that the fair value of our ordinary shares changed for each grant date because of the continued clinical development and advancement of our product candidate, which we believe resulted in a greater overall company valuation at each grant date. Information regarding each such issuance, on a pre-Reorganization basis, is included in the following table:

Year of issuance of equity	Instrument issued	Number of shares derived from the instrument issued	Number of options/warrants	Consideration ($)	Exercise price ($)	
2000	Ordinary shares	5,150		650,000		
2002	Options		53		1,075	
2005 2008	Ordinary shares upon conversion of convertible notes	1,703		3,596,778		
2012	Warrant		331		2,601	
2012	Options		331		2,601	
2013	Ordinary shares upon conversion of the Convertible Loan Agreement	1,432		3,724,462		
2013	Ordinary shares upon conversion of the Bridge Loans	701		1,824,300		
2013	Ordinary shares upon conversion of the Convertible Security Notes	707		4,717,641		
2013	Options		1,673		0.01	2,601
2013	Ordinary shares	46		120,000		

(*) The warrant was issued with several performance conditions to its exercise. The Company estimated that the conditional performances set forth in the warrant would not be met and accordingly did not record expenses due to such warrant, which expired in May 2013.

(**) The convertible loan agreement, dated December 21, 2011, by and among GHI, its shareholders and Shirat HaChaim Ltd., or the Convertible Loan Agreement, was deemed issued in January 2012 for accounting purposes and was classified as an equity instrument. In 2013, the Convertible Loan Agreement was converted into ordinary shares.

(***) The Convertible Security Notes were initially issued with a face value of $1.84 million. The Company revalued the Convertible Security Notes based on their fair value as a result of a modification of their conversion price in December 2013. For further elaboration see the notes to our financial statements contained elsewhere herein.

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Information regarding each such issuance, on a post-Reorganization basis, is included in the following table:

Year of issuance of equity	Instrument issued	Number of shares derived from the instrument issued	Number of options/warrants	Consideration ($)	Exercise price ($)
2000	Ordinary shares	3,754,350		650,000	
2002	Options		38,637		1.47
2005 2008	Ordinary shares upon conversion of convertible notes	1,241,487		3,596,778	
2012	Warrant		241,299		3.57
2012	Options		241,299		3.57
2013	Ordinary shares upon conversion of the Convertible Loan Agreement	1,043,928		3,724,462	
2013	Ordinary shares upon conversion of the Bridge Loans	511,029		1,824,300	
2013	Ordinary shares upon conversion of the Convertible Security Notes	515,403		4,717,641	
2013	Options		1,219,617		0.01 3.571
2013	Ordinary shares	33,534		120,000	

(*) The warrant was issued with several performance conditions to its exercise. The Company estimated that the conditional performances set forth in the warrant would not be met and accordingly did not record expenses due to such warrant, which expired in May 2013.

(**) The Convertible Loan Agreement was entered into in 2011, but for accounting purposes it was deemed issued in January 2012 and was classified as an equity instrument. In 2013, the Convertible Loan Agreement was converted into ordinary shares.

(***) The Convertible Security Notes were initially issued with a face value of $1.84 million. The Company revalued the Convertible Security Notes based on their fair value as a result of a modification of their conversion price in December 2013. For further elaboration see the notes to our financial statements contained elsewhere herein.

We believe that a significant factor contributing to the increase in the estimated fair value of our ordinary shares in this offering of $13.50 per Share is a result of our prior successful completion of a Phase IIa clinical trial of aramchol and the anticipated commencement of the proposed Phase IIb clinical trial of aramchol during 2014. Our last financing round was based upon our Phase I data and prior to the successful completion of our Phase IIa study. As such, the Company was valued as a Phase I clinical development stage company. This price per Share in this offering is based on the Company s valuation as a Phase II clinical development stage company with proof of concept and the potential for an additional 20 years of patent protection for our product candidate with respect to a new composition of matter patent application recently submitted by the Company, as opposed to a valuation based merely on safety data, as is the case for Phase I clinical development companies.

The intrinsic value of the Company s vested and unvested options outstanding as of February 27, 2014, based on the price per Share in this offering, was $16,482,318 and $2,803,120, respectively.

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Results of Operations

The table below provides our results of operations (which reflect the results of operations of GHI, our predecessor, prior to the Reorganization) for the year ended December 31, 2013 as compared to the year ended December 31, 2012 and for the year ended December 31, 2012 as compared to the year ended December 31, 2011.

	Year ended December 31,		
	2011 (audited)	2012 (audited)	2013 (audited)
	(In thousands, except per share data)		
Research and development expenses	$ 1,326	$ 2,443	$ 7,207
General and administrative expenses	151	694	7,355
Capital Loss			10
Operating loss	1,477	3,137	14,572
Financial expenses, net	3	6	2,912
Operating loss post-finance expense & other income, net	1,480	3,143	17,484
Taxes on income	2	6	1
Net loss	$ 1,482	$ 3,149	$ 17,485
Loss per share	$ 216.26	$ 459.51	$ 2,514.38

Research and Development Expenses

Our research and development expenses amounted to $7.2 million during the year ended December 31, 2013, representing an increase of $4.8 million, or 195%, as compared to such expenses for the comparable prior year. This increase primarily resulted from stock based compensation of $4.3 million and increased studies in connection with aramchol for the treatment of NASH in obese patients with insulin resistance.

Our research and development expenses amounted to $2.4 million for the year ended December 31, 2012, representing an increase of $1.1 million, or 84%, as compared to such expenses for the year ended December 31, 2011. This increase primarily resulted from additional chemistry and drug formulation studies in connection with aramchol for the treatment of NASH in obese patients with insulin resistance.

General and Administrative Expenses

Our general and administrative expenses amounted to $7.4 million during the year ended December 31, 2013, representing an increase of $6.7 million, or 960%, as compared to such expenses for the comparable prior year period. This increase primarily resulted from an increase in salaries and benefits as a result of greater non-cash stock-based compensation to employees of $6.4 million and greater professional fees of $496,000.

Our general and administrative expenses amounted to $694,000 for the year ended December 31, 2012, representing an increase of $543,000, or 360%, as compared to such expenses for the year ended December 31, 2011. This increase primarily resulted from an increase in salaries and benefits as a result of greater non-cash stock-based compensation to our Chairman of $208,000, greater payroll expenses of $154,000 and greater professional fees of $58,000.

Operating Loss

As a result of the foregoing research and development and general and administrative expenses as well as our failure to generate revenues since our inception, for the year ended December 31, 2013 our operating loss was $14.6 million, representing an increase of $11.4 million, or 364%, as compared to our operating loss for the comparable prior year period. This increase primarily resulted from an increase in non-cash stock-based compensation to employees of $10.8 million as compared to $208,000 for the comparable prior year period.

Our operating loss for the year ended December 31, 2012 was $3.1 million, representing an increase in our operating loss of $1.7 million, or 112%, as compared to our operating loss for the year ended December 31, 2011. The increase was primarily due to an increase in research and development expenses.

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Financial Expense, Net

In addition to bank fees and loan interest, the Company recorded new convertible notes at fair value. The difference between the fair value of the new convertible notes and the net carrying amount of the extinguished notes, in the amount of approximately $2.9 million was recorded in the statement of operations report as a financial expense for the year ended December 31, 2013.

Net Loss

As a result of the foregoing research and development and general and administrative expenses as well as our failure to generate revenues since our inception, for the year ended December 31, 2013 our net loss was $17.5 million, representing an increase of $14.3 million, or 455%, as compared to our net loss for the comparable prior year period. The increase was primarily due to an increase in non-cash stock-based compensation to employees and finance expenses.

Our net loss for the year ended December 31, 2012 was $3.1 million, representing an increase of $1.7 million, or 112%, as compared to our net loss for the year ended December 31, 2011. The increase was primarily due to an increase in research and development expenses in connection with chemistry and drug formulation studies.

Liquidity and Capital Resources

Overview

We have incurred substantial losses since our inception. As of December 31, 2013, we had an accumulated deficit of approximately $27.6 million and negative working capital (current assets less current liabilities) of $1.5 million. We expect that losses will continue for the foreseeable future.

As of December 31, 2013, we had cash and cash equivalents of $137,000 as compared to $718,000 as of December 31, 2012. This decrease of $581,000 is primarily due to our net loss of $17.5 million during the year ended December 31, 2013, an increase in trade payables in the amount of $954,000, an increase in accounts receivable in the amount of $228,000, the issuance of a convertible note in the amount of $1.8 million, a non-cash financial expense due to convertible note modification in the amount of $2.9 million and a stock based compensation expense in the amount of $10.9 million.

As of December 31, 2012, we had cash and cash equivalents of $718,000 as compared to $146,000 as of December 31, 2011. This increase of $572,000 is primarily due to the issuance of a capital note in the amount of $3.7 million and a net loss of $3.1 million in the year ended December 31, 2012.

We had negative cash flow from operating activities of $2.5 million for the year ended December 31, 2013 as compared to a negative cash flow from operating activities of $3.1 million for the year ended December 31, 2012. The negative cash flow from operating activities for the year ended December 31, 2013 is mainly attributable to our net loss of $17.5 million, a non cash financial expense due to convertible note modification in the amount of $2.9 million and a stock based compensation expense in the amount of $10.9 million.

We had negative cash flow from operating activities of $3.1 million for the year ended December 31, 2012 as compared to a negative cash flow from operating activities of $721,000 for the year ended December 31, 2011. The

negative cash flow from operating activities for the year ended December 31, 2012 is mainly attributable to our net loss of $3.1 million less a non-cash share-based compensation expense of $208,000.

We had positive cash flow from investing activities of $3,000 for the year ended December 31, 2013 as compared to a negative cash flow from investing activities of $32,000 for the year ended December 31, 2012. The positive cash flow from investing activities for the year ended December 31, 2013 was due to the sale of equipment in the amount of $16,000 less the investment in such equipment in the amount of $13,000, while the negative cash flow from investing activities for the year ended December 31, 2012 was due to the investment in such equipment.

We had negative cash flow from investing activities of $32,000 for the year ended December 31, 2012 as compared to a positive cash flow from investing activities of $84,000 for the year ended December 31, 2011.

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The negative cash flow from investing activities for the year ended December 31, 2012 was due to the purchase of equipment, while the positive cash flow from investing activities for the year ended December 31, 2011 was due to the sale of negotiable securities.

We had positive cash flow from financing activities of $1.9 million for the year ended December 31, 2013 as compared to a positive cash flow from financing activities of $3.7 million for the year ended December 31, 2012. The positive cash flow from financing activities for the year ended December 31, 2013 was primarily due to the issuance of a convertible note in the amount of $1.8 million, while the positive cash flow from financing activities for the year ended December 31, 2012 was primarily due to the issuance of a capital note in the amount of $3.7 million.

We had positive cash flow from financing activities of $3.7 million for the year ended December 31 2012 as compared to a positive cash flow from financing activities of $650,000 for the year ended December 31, 2011. The positive cash flow from financing activities for the year ended December 31, 2012 was primarily due to the issuance of a capital note in the amount of $3.7 million, while the positive cash flow from financing activities for the year ended December 31, 2011 was primarily due to the issuance of convertible notes in the amount of $589,000.

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. Nevertheless, we will require significant additional financing in the future to fund our operations if and when we progress into Phase III trials of aramchol and clinical trials for other indications, obtain regulatory approval of aramchol and commercialize the drug.

Current Outlook

Our independent registered public accounting firm s report to our financial reports for the fiscal year ended December 31, 2013, states that there is a substantial doubt that we will be able to continue as a going concern. Furthermore, according to our estimates and based on our budget, if we are not successful in obtaining additional capital resources, there is substantial doubt that we will be able to continue our activities beyond 2014. Even if we are able to raise funds in the offering contemplated herein, we believe that we will need to raise significant additional funds before we have any cash flow from operations, if at all.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. 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. Nevertheless, we will require significant additional financing in the future to fund our operations, including if and when we progress into Phase III trials of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance and clinical trials for other indications, obtain regulatory approval for aramchol and commercialize the drug. We currently anticipate that, assuming consummation of the current offering, we will utilize approximately $10.0 million for clinical trial activities over the course of the next 12 months. Our future capital requirements will depend on many factors, including:

the progress and costs of our preclinical studies, clinical trials and other research and development activities;
the scope, prioritization and number of our clinical trials and other research and development programs;
the amount of revenues and contributions we receive under future licensing, development and commercialization arrangements with respect to our product candidate;
the costs of the development and expansion of our operational infrastructure;
the costs and timing of obtaining regulatory approval for our product candidate;
the ability of us, or our collaborators, to achieve development milestones, marketing approval and other events or

developments under our potential future licensing agreements;

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the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
the costs and timing of securing manufacturing arrangements for clinical or commercial production;
the costs of contracting with third parties to provide sales and marketing capabilities for us;
the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or platforms;
the magnitude of our general and administrative expenses; and
any cost that we may incur under future in- and out-licensing arrangements relating to our product candidate.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through the net proceeds from the current offering, debt or equity financings or by out-licensing applications of our product 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 product candidate. This may raise substantial doubts about the Company s ability to continue as a going concern.

Contractual Obligations

The following table summarizes our significant contractual obligations (which reflect the significant contractual obligations of GHI, our predecessor, prior to the Reorganization) at December 31, 2013.

	Total	Less than 1 year	1 3 years	More than 3 years
	(in thousands)			
Facility Leases	$ 33	$ 33	$	$
Termination payment	153			153
Total	$ 186	$ 33	$	$ 153

We did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment, as of either December 31, 2012 or 2013.

Off-Balance Sheet Arrangements

The Company currently does not have any off-balance sheet arrangements that have had, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

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, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. Our market risk exposure is primarily a result of foreign currency exchange rates. Approximately 47% of our expenses are denominated in Euros. Changes of 5% and 10% in the U.S. dollar to Euro exchange rate will increase/decrease our operation expenses by 2.4% and 4.7%, respectively.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the Euro mainly against the U.S. dollar because most of our expenses are denominated in Euros. Our Euro expenses consist principally of payments made to sub-contractors and consultants for preclinical studies, clinical trials and other research and development activities. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. Our financial position, results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange

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rates. Our results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

To date, we have not engaged in hedging 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.

Trend Information

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this Management s Discussion and Analysis of Financial Condition and Results of Operations.

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BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of a novel, once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones utilizing our proprietary first-in-class synthetic fatty-acid/bile-acid conjugate, or FABAC, called aramchol. We believe that aramchol has the potential to be a disease modifying treatment for fatty liver disorders, including Non-Alcoholic Steato-hepatitis, or NASH, which is a chronic disease that we believe constitutes a large unmet medical need.

NASH is a severe form of Non-Alcoholic Fatty Liver Disease, or NAFLD, in which patients suffer from inflammation and fat accumulation in the liver. NAFLD, which is the first stage of liver disease, is characterized by an accumulation of more than 6% of fat in the liver of people who drink little or no alcohol, and it is mostly associated with obesity or genetic predisposition, as well as in people with a combination of a high fat, fructose-rich diet and a sedentary lifestyle. Recent studies suggest that whereas NAFLD can be a benign condition, NASH may lead to progressive fibrosis that dramatically increases the risk of late-stage severe liver diseases, such as cirrhosis, carcinoma and end-stage liver disease, each potentially requiring liver transplantation. NASH is also associated with increased risk for metabolic and cardiovascular diseases. Both the medical community s and the public s awareness of NASH and its complications, as well as its economic burden, have increased in recent years. According to a recent workshop held by the AASLD and the FDA entitled Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease (NAFLD), the FDA is currently working on guidelines for the development of therapies for the treatment of NASH. There is currently no approved medical treatment for NASH.

According to the Journal of Gastroenterology and Hepatology in 2013, NAFLD is believed to affect up to 30% of the population in developed countries and up to 75% of Western populations with diabetes and obesity. Also according to the Journal of Gastroenterology and Hepatology in 2013, approximately 12% of the general population in the United States and in the five most-populated countries in the EU, the United Kingdom, France, Spain, Germany and Italy, has NASH. According to the Journal of Hepatology in 2008, and as summarized in the Journal of Hepatology in 2010, the risk that persons with NASH will suffer a liver disease-related death is ten-times higher than that of the general population, and according to these sources, as well as the Journal of Gastroenterology in 2005, NASH increases overall mortality by between 35% and 85%. Also according to the Journal of Gastroenterology and Hepatology in 2013, approximately one third of all NASH patients will develop liver cirrhosis, and nearly one million people with NASH are projected to progress to liver cirrhosis between 2006 and 2015. Additionally, according to the Journal of Gastroenterology in 2011, the proportion of liver transplants attributed to NASH in the United States increased from 1.2% in 2001 to 9.7% in 2011, establishing NASH as the third leading cause of liver transplantation in the United States. Furthermore, according to the Journal of Digestive Diseases in 2011 and the Journal of Hepatology in 2010, NASH will become the leading cause of liver transplantation in the United States by 2020. Michael Charlton and other scientists at the Mayo Clinic project NASH to surpass hepatitis C as the leading cause of hepatocellular carcinoma in the near future. NASH patients are also twice as likely to die from cardiovascular disease as the global general population.

According to Global Data, the growing global rate of obesity and diabetes as well as the expected launch of new NASH specific treatments will increase the NASH market from $233.0 million in off-label sales in the United States and the five most-populated EU countries in 2012 to $863.0 million in total sales by 2017, with a CAGR of 30%. Based on our extrapolation from the estimated total direct economic cost over the respective lifetimes of the current NASH population in the United States aged 45 to 74, which cost was presented in the Journal of Hepatology in 2006,

we estimate that the financial burden of NASH in the United States alone may reach approximately $41 billion within the next decade. Furthermore, according to studies published in the Journal of Gastroenterology in 2008, the progression to NASH increases the five year direct and indirect healthcare costs for patients with NAFLD by 26%.

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The estimated size of the NASH patient population in the United States and in the five most-populated EU countries is presented in the diagram below.

We are initially developing aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance. These patients are at the highest risk of developing both the cardiovascular and hepatic complications associated with NASH. Aramchol is a synthetic conjugate of cholic acid, or a type of bile acid, and arachidic acid, or a type of saturated fatty acid, both of which, in their non-synthetic forms, are naturally occurring. The conjugated molecule acts upon important metabolic pathways, reducing fat accumulation in the liver and regulating the transport of cholesterol, which is essential for maintaining cholesterol balance in the body. The ability of aramchol to decrease liver fat content may also reduce the risk of cardiovascular complications associated with NASH. Independent third-party epidemiologic studies have shown that certain levels of fat reduction may reduce, and ultimately eliminate, liver inflammation in patients who have undergone bariatric surgery or other weight loss programs. We believe that aramchol s ability to reduce liver fat without observable adverse side effects in our studies to date will enable it to be an effective treatment for NASH and the hepatic and cardiovascular complications associated therewith.

During the second half of 2014, we intend to begin a multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase IIb clinical trial of aramchol in 240 biopsy-diagnosed NASH patients who also suffer from obesity and insulin resistance. Our planned Phase IIb clinical trial for aramchol in NASH patients is in accordance with the study design recommended by the MHRA and has been deemed acceptable by BfArM and deemed satisfactory by ANSM. The study design has recently been confirmed by the FDA in a written pre-IND advice as acceptable for a Phase IIb study. The BfArM and ANSM also confirmed, in minutes of each of their respective scientific advisory meetings, that if successful, this Phase IIb trial may serve as a basis for Phase III pivotal trials of aramchol. The FDA and MHRA invited us to discuss the next steps in the development of aramchol after we analyze the results of the Phase IIb study. If the Phase III trials are successful, we intend to submit an NDA to the FDA and an MAA to the EMA for the approval of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance in the United States and Europe. We currently expect results from the Phase IIb trial to be available

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in the second half of 2016. During this Phase IIb trial and once 120 patients complete six months of treatment, we intend to conduct an interim analysis of the efficacy and safety of aramchol based on blood markers of inflammation. We currently expect results from the interim analysis to be available in the second half of 2015. We also currently plan to conduct, but provide no assurance that we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of NASH in children, which will be preceded by further preclinical studies and PK studies, and an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones.

To date, we have successfully completed three clinical trials of aramchol. The first was a single dose, double-blind, placebo-controlled, Phase Ia study with ascending doses of aramchol in healthy volunteers in one center in Israel. All doses proved to be well-tolerated and no adverse side effects were observed in our studies to date. An additional Phase Ib repeated dose trial completed on healthy volunteers in one center in Israel also showed that aramchol has no observable adverse side effects and confirmed the suitability of a once-daily dose of aramchol. A multi-center, randomized, double-blind, placebo-controlled Phase IIa trial of aramchol in 60 NAFLD and NASH patients in 12 centers in Israel, whose study design was deemed acceptable by the FDA in 2007 at a pre-IND scientific advisory meeting, demonstrated that aramchol reduced liver fat in a dose dependent manner, as evidenced by a statistically significant reduction of liver fat over a three month treatment period of once-daily 300 mg doses of aramchol, and induces positive trends of changes in several metabolic parameters.

Based on our Phase IIa proof-of-concept results, we established a development plan that we believe may confirm that aramchol (i) is safe, (ii) can be administered as a once-daily oral therapy, (iii) targets NASH, (iv) can effectively treat inflammation and thus prevent the progression of NASH and (v) can treat the underlying condition of NASH, metabolic syndrome, by improving insulin resistance and other parameters of metabolic syndrome, such as HOMA levels, or homeostatic model assessment levels, which is a method used to quantify insulin resistance and beta-cell function, which are each biological markers of metabolic syndrome, and adiponectin levels. In the future and as part of our vision for aramchol, we intend to conduct long-term studies to demonstrate that aramchol may prevent the progression of NASH to end-stage liver disease, thus reducing the occurrence of liver transplantations, liver and cardiovascular morbidity and the overall economic burden of NASH and its late-stage complications on global health systems and society in general. This vision is illustrated in the following diagram.

Our Development Pipeline

Based on the potential fat-reducing effects of aramchol in the human liver, we are considering additional indications with meaningful potential market opportunities, with the view of expanding aramchol s therapeutic

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applications to the treatment of NASH in children, cholesterol gallstones, CASH and feline fatty liver. The pipeline chart below shows the current stage of development of aramchol for each of these indications and the next planned clinical trial in respect of each such indication, as applicable, as well as the preclinical programs for aramchol.

Indication	Planned Next Clinical Trial	Expected Number of Patients	Anticipated Key Events
Non-Alcoholic Steatohepatitis (NASH)	Phase IIb	240 patients	Initiate Phase IIb trial in the second half of 2014 |B2 Conduct interim analysis of 120 patients in Phase IIb trial who have completed six months of treatment in the second half of 2015 |B2 Release top-line results from Phase IIb trial in the second half of 2016
Cholesterol Gallstones	Phase IIa	20 patients	Initiate Phase IIa trial in the second half of 2014 |B2 Release top-line results from Phase IIa trial in the second half of 2014
NASH in Children	Preclinical	To be determined	Pediatric Investigational Plan submission in the first half of 2014 |B2 Initiate Phase I trial in the second half of 2015

Our Competitive Strengths

The pharmaceutical industry is characterized by rapidly evolving technology, intense competition and a highly risky, costly and lengthy research and development process. Adequate protection of intellectual property, successful product development, adequate funding and retention of skilled, experienced and professional personnel are among the many factors critical to success in the pharmaceutical industry. We believe we are strategically positioned to address the unmet medical needs of NASH patients who also suffer from obesity and insulin resistance. Our competitive strengths include:

A once-daily oral drug without observable adverse side effects in development for the chronic treatment of NASH. We believe that the characteristics of aramchol, including its ability to reduce liver fat content without observable adverse side effects in our studies to date, which we believe may result in

an anti-inflammatory effect, its ability to modulate the transport of cholesterol in the body and simple and convenient delivery through once-daily oral administration, position it well against the competition in the treatment of NASH. We believe that such characteristics may also lead to aramchol's acceptance and adoption by the medical community, including patients, as an alternative to the medical treatments used today, which are not approved by applicable regulatory authorities for NASH as their efficacy has not been proven in well-designed clinical studies. We believe aramchol is well-positioned against drugs in development for NASH, some of which may require intravenous delivery or may cause adverse events, such as itching, which can be highly inconvenient for patients with chronic diseases, such as NASH, and may result in low patient compliance.

Extensive knowledge and expertise in the treatment of liver diseases, the development of FABACs and working with lipid molecules. We believe our management team, scientific advisors, personnel and affiliates, including our subsidiaries, have extensive knowledge and experience in the treatment of liver diseases and cholesterol gallstones, developing FABACs, such as aramchol, for the treatment of liver diseases and cholesterol gallstones and working with lipid molecules, which due to their special physiochemical characteristics, are difficult to synthesize, develop and work with. We believe that such knowledge and expertise makes us competitive in the NASH and cholesterol gallstones fields.

Non-invasive diagnostic tools for the assessment of aramchol s effect. If we are successful in our clinical trials in correlating fat reduction in the liver as measured by NMRS, an FDA validated

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and commonly used test for the measurement of liver fat content, with aramchol s effect on inflammation in the liver, NMRS may become a non-invasive biomarker that is able to measure the effect of aramchol in patients following treatment with the drug. Additionally, in collaboration with Enterome, we intend to develop a non-invasive biomarker that is able to predict individual responses to aramchol prior to treatment. We also are collaborating with Zora in order to identify the lipidomic profile for NASH patients responding to aramchol treatment. We believe that such biomarkers and profiles may facilitate aramchol's market penetration and accelerate its acceptance and adoption by the medical community and NASH patients as a treatment option, thereby increasing our competitiveness in the NASH market.

Our Strategy

Our strategy is to build a specialized biopharmaceutical company that discovers, develops and commercializes novel FABAC drugs and potentially other molecules for the treatment of liver diseases and cholesterol gallstones, beginning with the treatment of fatty liver disorders, primarily NASH, and cholesterol gallstones. We focus on drugs and drug conjugates for liver diseases and cholesterol gallstones with global market potential and we seek to create global partnerships with academic institutions and biotechnology or pharmaceutical companies to effectively assist us in developing our portfolio and marketing our products. Using this approach, we have successfully advanced aramchol into various stages of clinical development. Key elements of our strategy include:

Continuing to advance our development of aramchol for the treatment of NASH. Our development of aramchol for the treatment of NASH currently includes the planned Phase IIb trial of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance. If our planned Phase IIb trial is successful, the results will serve as a basis for potential Phase III pivotal trials in Europe and Israel for the same indication and as a basis for discussion for potential Phase III pivotal trials in the United States for the same indication. If the Phase III trials are completed successfully, we intend to seek regulatory approval of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance in the United States and Europe.

Exploring other indications for the use of aramchol, which currently includes the treatment of NASH in children and cholesterol gallstones. We currently plan to conduct, but provide no assurance that we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of NASH in children, which will be preceded by further preclinical studies, PK studies and a Phase I clinical trial of aramchol in children, and an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones.

Establishing a development and commercialization partnership for aramchol if we successfully complete the Phase IIb trial or after the successful completion of the first of the potential Phase III trials of aramchol for the treatment of NASH. Following applicable regulatory approval, which we provide no assurance we will receive, we intend to commercialize aramchol, and our other future products, through out-licensing agreements with major pharmaceutical or biotechnology companies that possess experience, resources and infrastructure to execute a successful market launch and provide sales support for aramchol. Such companies may perform any or all of the following tasks: completing development, securing regulatory approvals, manufacturing, marketing and sales. We may ultimately, in the future, consider building an internal commercial infrastructure.

Advancing existing collaborations for the discovery and validation of diagnostic tools and biomarkers for the diagnosis of liver disease. We intend to advance our existing collaborations and strategic arrangements for the discovery and validation of non-invasive diagnostic tools and biomarkers for the diagnosis of liver disease, including NASH. We are currently collaborating with Enterome on the development of a non-invasive biomarker which, if successful, may help to stratify patients for our planned Phase III clinical trial and may help to predict individual responses to aramchol for the treatment of liver diseases. Enterome also granted us a right of first refusal, exercisable upon completion of our Phase IIb clinical trial, to enter into a business transaction with

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Enterome regarding the commercial exploitation of its metagenomic profiles and metagenomic data generated during the collaboration. In addition, we are collaborating with Zora in order to identify the lipidomic profile for NASH patients responding to aramchol treatment. Zora granted us a right of first discussion, exercisable upon completion of our Phase IIb clinical trial, to enter into a business transaction with Zora regarding the commercial exploitation of its NASH disease clinical diagnostic tool based upon the data generated during our collaboration.

In-licensing or acquiring additional drug candidates for the treatment of liver diseases. Aramchol is directed at the treatment of liver diseases, particularly NASH, that have major global markets and cholesterol gallstones. Our intent is to explore opportunities to in-license or acquire other drugs and/or drug conjugates for the treatment of liver diseases.

We believe that our strategy will increase the likelihood of advancing clinical development and potential commercialization of aramchol, as well as increase awareness of liver disease and cholesterol gallstones, our brand and our potential market share.

Overview of NAFLD and NASH

NAFLD. NAFLD is a spectrum of conditions characterized by the accumulation of fat in the liver, encompassing fatty liver, a relatively benign increase in liver fat content, NASH, or fat infiltration and inflammation of the liver, and liver cirrhosis, or scarring of the liver tissue. Although some fat in the liver is normal, if fat comprises more than 6% of the liver, it may lead to inflammation and subsequent liver disease. In some cases, over time, liver cells may be replaced by scar tissue, which causes cirrhosis. When this happens, the liver is unable to function properly, necessitating a liver transplant or leading to liver cancer, and potentially liver-related death. The following diagram demonstrates the progression of liver disease.

According to the Journal of Gastroenterology and Hepatology in 2013, NAFLD is believed to affect up to 30% of the population in developed countries, and up to 75% of Western populations with diabetes and obesity. According to the World Gastroenterology Organization, in 2012, 30%, 25%, 25% and 15%, respectively, of the general population in each of the United States, Europe, the Middle East and Asia, respectively, had NASH.

Associated with the Western diet, which is rich in processed foods with high fat and sugar content, and a sedentary lifestyle, NAFLD s prevalence is rapidly growing in parallel with metabolic syndrome, obesity and diabetes, each of which are on the rise in Western countries. Metabolic syndrome is a serious health condition caused by obesity, physical inactivity and genetic factors that results in a higher risk of cardiovascular disease, diabetes, stroke and NAFLD. According to the Journal of Gastroenterology and Hepatology in 2013, NAFLD is associated with insulin resistance and its physical and biochemical manifestations, such as obesity, visceral adiposity, type 2 diabetes, hypertriglyceridemia and arterial hypertension. Recently, the medical community has widely come to consider NAFLD as the liver disease of metabolic syndrome, which is the cause of atherosclerosis and its associated complications. Concordant studies over the last five years in Europe and Japan have demonstrated that over a follow-up period of five to six years, individuals with NAFLD also develop major cardiovascular complications, such as myocardial infarction, more frequently than those without NAFLD. Further, the Journal of Gastroenterology and Hepatology in 2013 suggests a causal relationship between the progression of metabolic syndrome and the occurrence of NAFLD. The Journal of Gastroenterology and Hepatology also notes that the amount of liver fat influences the severity of insulin resistance, such that patients with fat accumulation in the liver have substantially more insulin resistance than

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those without such accumulation. Moreover, according to the Journal of Gastroenterology and Hepatology in 2013, patients with NAFLD develop atherosclerosis, or hardening of the arteries, approximately five to ten times earlier than those without NAFLD. It is therefore considered by the medical community that NAFLD is not only a manifestation of metabolic syndrome, but may also be involved in its development and severity. The current management of NAFLD demands lifestyle changes such as weight reduction and physical activity, which are hard to achieve and long-term compliance is difficult.

NASH. NASH is a severe form of NAFLD characterized by inflammation in the liver in addition to the presence of excess fat. A subset of approximately 30% to 50% of individuals with NAFLD in all age groups, including children, develop NASH, although this more often occurs in obese individuals. Independent third-party studies suggest that whereas simple fatty liver can be a benign condition, in NASH patients, for reasons that are still not completely understood, the fat build-up in the liver induces chronic inflammation which leads to progressive fibrosis that can lead to cirrhosis with a high risk of carcinoma and to end-stage liver disease. According to the Journal of Gastroenterology, NASH is currently the third leading indication for liver transplantation in the United States, and according to the Journal of Digestive Diseases in 2011 and the Journal of Hepatology in 2010, NASH will become the leading cause for liver transplantation in the United States by 2020.

According to GlobalData, the growing global rate of obesity and diabetes as well as the expected launch of new NASH specific treatments will increase the NASH market from $233.0 million in off-label sales in the United States and the five most-populated EU countries in 2012 to $863.0 million in total sales by 2017, or a CAGR of 30%.

NASH is often discovered incidentally, frequently by observation of elevated liver enzyme levels in blood tests. NASH patients may be asymptomatic or suffer from fatigue, with other symptoms occurring as the liver disease advances. Diagnosis of NASH is based on the exclusion of other reasons for liver disease, such as the use of medications, viral hepatitis or excessive use of alcohol; followed by non-invasive imaging tests, such as ultrasound, Computed Tomography scan, or CT scan, and Magnetic Resonance Imaging, or MRI. Liver biopsy is currently the standard procedure for the diagnosis of NASH.

The underlying pathophysiology, or the explanation of the physiological processes or mechanisms whereby abnormal or undesired conditions develop and progress, of NASH is not well understood. The disease is multifactorial, involving both genetic and environmental factors that regulate lipid metabolism and the transportation of fat to, within and from the liver cells. Insulin resistance and subsequent hyperinsulinemia, or increased blood insulin levels as compared to blood glucose levels, lead to alterations in the hepatic metabolism of free fatty acids and ultimately to an accumulation of lipids in the liver cells. As the disease progresses, persistent fatty infiltration and inflammation cause liver damage marked by fibrosis and gradual loss of normal liver cells, which in turn could lead to cirrhosis with a high risk of carcinoma and end-stage liver disease.

Beside its hepatic complications, NASH is also associated with increased risk for the cardiovascular complications associated with metabolic syndrome. A position statement on NAFLD and NASH from the European Association for the Study of the Liver s, or the EASL, 2009 Special Conference found extra-hepatic complications of NAFLD and NASH. The EASL position statement noted that [b]eyond damage to the liver, steatosis can also worsen and/or induce insulin resistance, worsen glycemic control in patients with type 2 diabetes, and predict subsequent development of metabolic syndrome; it is also associated with increased cardiovascular risk and events. The long-term outcomes of patients with NASH have been reported in several studies, whose findings can be summarized as follows: (a) patients with NAFLD have increased overall mortality compared to matched control populations; (b) the most common cause of death in patients with NASH is cardiovascular disease; and (c) patients with NASH have an increased liver-related mortality rate.

Currently Available Treatment Options for NASH

Modification of risk factors, such as obesity and hyperlipidemia, and proper diabetic control is generally recommended for the treatment of NASH, and the standard of care includes lifestyle changes to promote weight loss, including low-calorie, low-fat diets and physical activity. Although weight loss can be potentially significant in delaying the progression of NASH, we believe that for most individuals, it is generally very difficult to maintain over the long-term, even following bariatric surgery.

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There are currently no drugs approved by regulatory authorities for the treatment of NASH. Even though certain drugs, such as insulin sensitizers and antihyperlipidemic agents, are prescribed for some NASH patients, they are not approved for the treatment of NASH and their efficacy has not been proven in well-designed clinical studies. Such prescription or use of unapproved drugs is typically known as off-label prescription or use. According to press releases issued in mid-2011 by the FDA and EMA, the use of other drugs that have historically also been used off-label to treat NASH has been restricted due to their severe side effects, including adverse cardiovascular effects and liver toxicity, or suspected carcinogenicity. Bariatric surgery can be performed in obese patients with NASH, but is not an established procedure to treat NASH. Lastly, vitamin E was found to be beneficial for non-diabetic patients with biopsy proven NASH, but not for diabetics with NASH, NAFLD or liver cirrhosis. As such, the use of vitamin E is fairly limited.

Based on the foregoing, we believe that there is a significant unmet need for a NASH-specific therapy. We believe that aramchol has the potential to provide significant benefits in the treatment of this liver disease due to its ability to reduce liver fat in a dose dependent manner, lack of observable adverse side effects in our studies to date and ease of use through once-daily oral administration. Moreover, based in part on the Journal of Gastroenterology and Hepatology, we believe the increasing rates of diabetes and obesity worldwide likely means that a significant number of patients will be eligible for, and will be interested in, receiving a new therapy for the treatment of NASH if it becomes available on the market.

Aramchol for NASH

Overview

Our product candidate, aramchol, is a first-in-class synthetic FABAC which we are initially developing for the once-daily oral treatment of NASH in patients who also suffer from obesity and insulin resistance.

Early in its development, aramchol s ability to modulate hepatic lipid metabolism was observed and validated in numerous preclinical trials with different animal species. Mice fed a high fat diet and treated with aramchol did not develop fatty liver, as opposed to the control mice that were fed a high fat diet, but were not treated with aramchol, in which fatty liver was observed. In such early studies, we also observed that the mechanism of this effect was not a result of malabsorption of fat in the intestines because the FABAC-treated mice gained weight throughout the test periods to a similar degree as the control mice. This led us to conclude that FABAC therapy triggers a beneficial modulation of intra-hepatic lipid metabolism and thus reduces liver fat content. The images below show the reduction of liver fat content in rodents after treatment with aramchol.

In *in vitro* studies, aramchol partially inhibited the Stearoyl-Coenzyme A Desaturase1, or the SCD1 enzyme, an enzyme recognized as playing an important role in the metabolism of fatty acids. The SCD1 enzyme is essentially the gateway that regulates the use and storage of fat in the body by converting saturated fatty acids to monounsaturated fatty acids. Experimental animal studies showed that inhibition of the SCD1 enzyme protects against diet-induced obesity, hepatic steatosis, or fatty liver, and insulin resistance by

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instructing the body to use, rather than store, all fatty acids. However, various animal studies have indicated that complete SCD1 enzyme inhibition has dangerous side effects, such as inflammation, atherosclerosis and pancreatic beta cell dysfunction. As observed by us in our studies and subsequently published in the European Journal of Gastroenterology and Hepatology and Archives of Medical Research in 2008 and 2010 respectively, one of aramchol s unique characteristics is that it triggers a partial SCD1 enzyme inhibition without any significant adverse events.

Aramchol also has the ability to up-regulate ABCA1, an enzyme that induces reverse cholesterol transport. Each cell in the body has a specific receptor for cholesterol entry, the LDL receptor, and a transporter, the ABCA1 transporter, that pumps cholesterol out of the cell towards the HDL lipoprotein which transports it towards the liver to be excreted into the intestine. This pathway from the cell to the liver is called the reverse cholesterol transport and is essential for maintaining cholesterol balance in the body. Excess levels of bad cholesterol are deposited mainly in vascular walls, causing atherosclerosis, or a vascular disease in which an artery wall thickens as a result of the accumulation of calcium and fatty materials, such as cholesterol. Activation of the reverse cholesterol transport reduces the bad cholesterol deposited in vascular walls and is therefore beneficial. As published in the Biochemical Journal, the Archives of Medical Research and the Current Opinion in Lipidology in 2006, 2010 and 2010, respectively, in several experimental models in animals, aramchol has been shown in independent studies to increase ABCA1 activity by between 300% and 400%, thereby stimulating reverse cholesterol transport, reducing cholesterol levels and preventing atherosclerosis.

The Company expects aramchol to reduce and eventually eliminate liver inflammation by the mechanism of action described above, while also mitigating cardiovascular comorbidities.

We are currently planning a Phase IIb trial to evaluate the efficacy and determine the safest and most efficient dose of aramchol as a novel treatment for NASH patients with obesity and insulin resistance. We plan to file an IND application with the FDA in the first quarter of 2014 in order to use the results of our previously conducted, and to be conducted clinical studies in Europe, Latin America and Israel, as a basis for the FDA's future approval to conduct the pivotal Phase III clinical trials and other clinical trials in the United States. We believe that filing the IND application could enable the first patent family covering aramchol s composition of matter to enjoy longer patent protection.

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Summary of Aramchol Clinical Trials

Aramchol: Results to date in, and future objectives of, clinical trials

Phase IIb Trial for Aramchol

We are currently planning our Phase IIb trial to determine the safest and most effective dose of aramchol for the treatment of NASH. In order to be eligible to participate in the Phase IIb trial, patients must be affected by NASH, as diagnosed by a biopsy, and also suffer from obesity, measured by a Body Mass Index between 26 and 35, and insulin resistance, measured by fasting plasma glucose levels of 100 mg/dl or greater. We are targeting this specific population as it is at the greatest risk of developing the complications that are associated with NASH. Although we do not expect aramchol to reduce the fibrosis levels of such patients, we intend to include both fibrotic and non-fibrotic patients in the trial. Patients will be randomized into one of three trial groups taking either one of two different once-daily oral doses of aramchol or a placebo. The treatment part of the trial is designed to be 12 months in duration and patients completing this phase will be observed for a three month follow-up period. This trial is designed to enroll 240 patients (89 patients in the 400 mg aramchol group, 89 patients in the 600 mg aramchol group and 62 patients in the placebo group) across approximately 40 clinical sites in Israel, Europe and Latin America, and we currently expect results from the trial to be available in the second half of 2016.

The primary endpoint of the 12 month double-blind portion of the trial is the achievement of a statistically significant reduction in liver fat concentration, which according to the trial design, would be a reduction in liver fat of 10% more than the placebo group, as measured by NMRS, which is a surrogate endpoint that is generally accepted by the FDA with respect to Phase I and Phase II NASH studies.

Secondary endpoints of the trial are the improvement in, or clearance of, NASH, as measured by biopsy and the NAFLD activity score, or NAS, which is defined as the improvement by a minimum of two points in the NAS with the contribution from more than one parameter, the achievement of improved liver and metabolic biomarker levels or, alternatively, the clearance of inflammation and no worsening of fibrosis. Exploratory endpoints such as FibroMax, which is a non-invasive comprehensive biomarker for the diagnosis of the most common liver diseases, including NASH, lipidomics, which is profiling that maps lipid structures, proteins and genes related to lipid composition in different body components, such as blood and liver tissue, and microbiota, which are microorganisms in the gut, are also included in order to assess the effect of aramchol by new non-invasive tests. The Company believes that finding a non-invasive test which correlates

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well with biopsy findings would significantly increase the likelihood of the future use of aramchol in an outpatient setting, where biopsies, which are expensive and painful, are not the standard of care.

During the trial, we will conduct an interim analysis for efficacy and safety with respect to 120 participants who have completed six months of treatment. An independent expert committee, the Data Safety and Monitoring Board, will review the interim safety data to determine whether emergent safety issues are present, and if so, whether they are dose-related. Depending on its severity, any emergent safety issues may warrant a suspension of the higher dose used in the trial or of the entire trial itself. Our pre-specified interim criterion for efficacy, which is based on inflammatory markers in blood tests, will be met if we observe a statistically significant (p-value 0.5) trend in at least one of the treatment groups as compared to the placebo group. If the interim criterion for efficacy is met, the trial will continue for the full period and number of patients as planned. If this result is not reached, however, the trial will be suspended and a futility analysis will be conducted.

On December 13, 2013, in connection with a pre-IND meeting that we requested with the FDA for aramchol for the treatment of NASH in obese patients with insulin resistance, the FDA provided a written response, or the FDA Response, regarding our planned Phase IIb study design, including its primary and secondary endpoints and inclusion and exclusion criteria. The FDA Response and prior correspondence confirmed that we may conduct our planned Phase IIb clinical trial, but recommended that we perform a PK and a food effect study prior to doing so. We currently plan to commence such PK and food effect studies in April 2014 and expect to obtain the results of such studies in the second half of 2014. Although we do not expect the results of these studies would prevent us from conducting our planned Phase IIb clinical trial, it is possible that we may be required to postpone the commencement of such clinical trial if the results of the PK and food effect studies indicate that we need to alter the dosage of aramchol to be administered in such clinical trial. The FDA also indicated that it will require data from nine month toxicology studies in animals prior to the initiation of any year-long clinical trial conducted within the United States. We are currently performing such a study. However, an interim analysis will be performed after six months, to support our planned Phase IIb clinical trial that will be performed in the EU, Israel and Latin America, where only six month toxicology data is required. We plan to commence the Phase IIb clinical trial immediately following the interim results of such toxicology study, in compliance with applicable EU, Israeli and Latin American guidelines, and anticipate continuing such study for an additional three months to obtain the data required by the FDA to conduct year-long clinical trials in the United States. The FDA also recommended that future clinical studies should be discussed at an end-of-Phase II meeting with the FDA to take place within three months from the date we complete the analysis of the results of the completion of our Phase IIb trial, where the data captured in such trial will be taken into consideration. The FDA Response further noted that we must discuss with the FDA a methodology for our drug development processes as our development of aramchol progresses to determine which surrogate endpoints, if any, the FDA will allow us to use to predict the clinical benefit of aramchol.

Potential Phase III Program for Aramchol

The development work we completed to date with regard to aramchol was deemed appropriate by the FDA, MHRA, BfArM and ANSM, and our Phase IIb study design is in accordance with the study design recommended by the MHRA, deemed acceptable by BfArM and deemed satisfactory by ANSM. In, addition, the FDA recently confirmed in a written pre-IND advisory letter that such study design is acceptable for a Phase IIb study. BfArM and ANSM also confirmed, in minutes of each of their respective scientific advisory meetings, that, if the Phase IIb trial is successful in reaching its primary endpoint, we may proceed to pivotal randomized, double-blind, placebo-controlled, Phase III trials. We expect the primary end-points of such trials to be the elimination of inflammation in the liver. The FDA, in the FDA Response, and the MHRA invited us to discuss the next steps in the development of aramchol after we complete the analysis of the results of our Phase IIb trial, where the data captured in such trial will be taken into

consideration. By the time we complete the Phase IIb study, we expect to have completed our ongoing nine-month chronic toxicity studies and planned PK and food-effect studies of aramchol, each as required by the FDA prior to initiating pivotal Phase III studies, as set forth in the FDA Response. We believe, but cannot be certain and do not provide assurance, that such approval in the United States will be considered under the FDA s Fast Track Development Program,

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which designation accelerates the development process and expedites the review of INDs that show promise in treating serious, life-threatening medical conditions for which no other drug either exists or is as effective.

Phase IIa Trial: Aramchol Treatment in NAFLD or NASH Patients

In January 2012, we completed a 60 patient multi-center, randomized, double-blind, placebo-controlled Phase IIa clinical trial of aramchol in patients with NAFLD or NASH between the ages of 18 and 75 in 12 centers in Israel. We have submitted the Phase IIa study results for publication in a peer reviewed medical journal and expect such results to be published in 2014. In accordance with the AASLD s guidelines for Phase IIa studies in NAFLD or NASH, the trial was performed in patients with either NAFLD or NASH, rather than only in NASH patients. The trial's primary efficacy endpoint was a reduction in liver fat content, and did not consider the inflammation or fibrosis, which can only be diagnosed by liver biopsy. We believe that the short study duration of three months of treatment followed by a one-month follow-up period did not warrant repeated biopsies. A summary of the demographic and baseline characteristics of the study population is presented in the following table. This table shows there were no significant differences in demographic baseline characteristics between the patients included in the study.

Summary of Demographic and Baseline Characteristics

		Aramchol 300 mg/d	Aramchol 100 mg/d	Placebo
Gender	**Male, N (%)**	14 (70.0)	15 (75.0)	14 (70.0)
	Female, N (%)	6 (30.0)	5 (25.0)	6 (30.0)
Race	**Caucasian, N (%)**	20 (100.0)	20 (100.0)	20 (100.0)
Age, mean ± SD (N), years		38.4 ± 14.6 (20)	39.8 ± 11.1 (20)	43.7 ± 13.2 (20)
Weight ± SD (N), kg		84.4 ± 15.5 (20)	88.2 ± 11.5 (20)	84.4 ± 11.3 (20)

N = number of patients

SD = standard deviation

The table below presents the NAFLD/NASH status, levels of fibrosis, alcohol use history and percentage of liver cells showing fatty change across the three treatment groups in the study, as well as the mean NAFLD activity score of each of the treatment groups in the study. The NAFLD activity score is an ordinal scoring system that takes into account the following elements: steatosis, or the amount of fat in the liver; lobular inflammation, or inflammation occurring in the lobes of the liver; and ballooning, or a form of liver cell death during which the cells increase in size. A higher NAFLD activity score reflects a more active disease. The data in the table shows there were no statistically significant differences at baseline in these parameters between the three treatment groups.

Disease History and Baseline Disease Status

		Aramchol 300 mg/d	Aramchol 100 mg/d	Placebo
Diagnosis, N (%)	**NAFLD**	18 (90.0)	17 (85.0)	18 (90.0)
	NASH	2 (10.0)	2 (10.0)	2 (10.0)
	Other	.	1 (5.0)	.
Fibrosis, N (%)	**0**	16 (80.0)	11 (55.0)	10 (50.0)
	1	4 (20.0)	5 (25.0)	5 (25.0)

2	.	2 (10.0)	3 (15.0)
3	.	2 (10.0)	2 (10.0)

		Aramchol 300 mg/d	Aramchol 100 mg/d	Placebo
Alcohol use history, N (%)	**Never consumed**	18 (90.0)	14 (70.0)	16 (80.0)
	Former consumer	2 (10.0)	2 (10.0)	1 (5.0)
	Currently consumes	.	4 (20.0)	3 (15.0)
Percentage of hepatocytes showing steatosis, or fatty change, mean ± SD (N)		54.8 ± 21.2 (20)	49.9 ± 24.3 (20)	45.2 ± 23.4 (20)
NAFLD activity score, mean ± SD (N)		0.7 ± 0.9 (20)	0.6 ± 1.0 (19)	0.8 ± 1.0 (20)

N = number of patients

SD = standard deviation

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The table above shows there were no significant differences at baseline regarding alcohol consumption and biopsy findings between the patients included in the study that could account for the differences at the end of the study. The trial evaluated the effects on liver fat content of 100 mg and 300 mg once-daily doses of aramchol compared to a placebo. At the end of the three month treatment period, statistically significant reductions in liver fat concentration as measured by NMRS, a noninvasive and sensitive method for quantification of the amount of fat in the liver, were observed in the 300 mg patient group. Specifically, a 12.57% mean liver fat content reduction was observed in the 300 mg group, as compared to a mean reduction of 2.89% in the 100 mg group and a mean increase of 6.39% in the placebo-treated patients, indicating that the effects of aramchol are dose-dependent, as demonstrated in the graph below, which presents the results with respect to the 57 patients who completed the entire treatment period and experienced no protocol violations.

Relative Change in MRS from Baseline After Three Months of Treatment

The difference between baseline and liver fat concentration at the end-of-treatment, as measured by NMRS, for patients diagnosed with NASH and with NAFLD is presented in the following table, which also presents the results with respect to the 57 patients who completed the entire treatment period and experienced no protocol violations.

Relative Change in Liver Fat Concentrations in the NASH and NAFLD Groups

Liver NMRS	Aramchol 300 mg/d Mean ± SD	Aramchol 100 mg/d Mean ± SD	Placebo Mean ± SD
NASH	-35.42 ± 50.09 (N = 2)	-9.82 ± 4.57 (N = 2)	19.24 ± 29.69 (N = 2)
NAFLD	-10.03 ± 18.22 (N = 18)	-6.05 ± 26.10 (N = 16)	4.88 ± 37.44 (N = 17)

N = number of patients

SD = standard deviation

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The following table presents the changes in liver fat concentration between baseline and at the end-of-treatment across the three treatment groups in the study for 57 patients who completed the entire treatment period and experienced no protocol violations.

Change in Liver Fat Concentration by NMRS Between Baseline and the End-of-Treatment

Liver NMRS	Aramchol 300 mg/d Mean ± SD N = 20	Aramchol 100 mg/d Mean ± SD N = 18	Placebo Mean ± SD N = 19
Pre-treatment	0.268 ± 0.073	0.248 ± 0.72	0.219 ± 0.080
Post-treatment	0.240 ± 0.094	0.230 ± 0.072	0.219 ± 0.070
Relative change (%)	-12.57 ± 22.14	-2.89 ± 28.22	6.39 ± 36.27
P value (within groups)*	0.016	0.4951	0.953
P value (between groups)**	0.0329	0.4682	

N = number of patients

SD = standard deviation

* P value is determined according to the Wilcoxon signed-rank test, or a non-parametric statistical hypothesis test, for the difference between baseline and post-treatment.

** P value is determined according to an analysis of covariance using the Dunnett method, or a multiple comparison method, for the difference between treatment group and placebo, adjusted for age, gender, baseline HbA1c, or blood glucose levels over the previous three months, and baseline weight.

The graph and two tables above show that the primary endpoint of the study was attained. The study reflected a statistically significant, dose dependent reduction in fat content in the livers of patients treated with aramchol, with a 19% difference between the 300 mg dose group and the placebo.

No statistically significant changes in body weight were observed between the three groups, suggesting that weight-loss did not influence the observed reduction in liver fat content experienced in the aramchol treated groups. The following table and graph presents the three treatment groups changes in weight from baseline to the end-of-treatment for all 60 randomized patients who received at least one dose of the study medication or placebo, but of whom only 58 patients completed the entire treatment period and experienced no protocol violations (the statistical analysis includes one patient who was subsequently excluded due to a violation in the inclusion criteria).

Change in Weight Between Baseline and the End-of-Treatment

Weight (Kg)	Aramchol 300 mg/d Mean ± SD N = 20	Aramchol 100 mg/d Mean ± SD N = 19	Placebo Mean ± SD N = 19
Pre-treatment	84.5 ± 16.2	88.4 ± 11.1*	84.2 ± 11.3*
Post-treatment	83.3 ± 16.1	88.2 ± 12.0	85.3 ± 12.1
change	-1.15 ± 2.25	0.18 ± 2.38	0.41 ± 2.39
P value**	0.183	0.9883	

N = number of patients

SD = standard deviation

* N = 20 for this data point

** P value is determined according to an analysis of covariance using the Dunnett method, or a multiple comparison method, for the difference between treatment group and placebo, adjusted for age, gender, diagnosis, baseline HbA1c and baseline weight.

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The table above shows that aramchol's effect on liver fat reduction was not due to weight loss. Weight loss of over 7% has a significant effect on liver fat content, but our study did not result in weight loss of such magnitude.

In addition, both treated patients and the placebo group showed a trend of reduction in alanine aminotransferase, or ALT, levels, which is a marker of hepatocellular injury and an indicator of liver disease. We believe that the reason the treated and placebo groups showed such a trend may be a result of the fact that the individuals in the placebo may have changed their lifestyle based on the guidance they received from the Company on adopting a healthy lifestyle. The aramchol treated groups ALT values relapsed 30 days post-treatment, indicating that after the cessation of aramchol treatment, the patients experienced recurring liver inflammation. The placebo group did not demonstrate a relapse in ALT levels. This supports the supposition that aramchol has a real biological effect.

Total cholesterol and low-density lipoproteins, or LDL, cholesterol levels were determined as safety parameters in our Phase IIa study. Differences between low-dose aramchol (100 mg/d), high-dose aramchol (300 mg/d) and the placebo were also analyzed for secondary efficiency endpoints. The graphs below show no statistically significant differences among the three treatment groups for cholesterol and LDL.

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Adiponectin is a protein that modulates metabolic processes, including the regulation of glucose levels and fatty acid breakdown in the body. Adiponectin has an anti-inflammatory and antifibrotic effect on the liver. Adiponectin deficiency, or low amounts of adiponectin, results in insulin resistance, glucose intolerance, abnormal levels of fat in the blood and vascular injury, all of which are characteristic of metabolic syndrome. The graph below shows the change in serum adiponectin levels from baseline during treatment. At the end of the three month treatment period, increased serum adiponectin levels were observed in the aramchol treated patient groups, indicating that aramchol increases serum adiponectin levels in a dose dependent manner, suggesting that aramchol may act as a protective factor for the prevention of metabolic syndrome, as increased serum adiponectin is itself such an independent protective factor.

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Change in Serum Adiponectin Levels from Baseline During Three Months of Treatment

The arterial endothelium is a target for the atherosclerotic process. Atherosclerosis is associated with endothelial dysfunction in the very early stages of the disease process. Several studies have shown that metabolic syndrome is associated with endothelial dysfunction as an early pathogenic event. Thus, assessing endothelial function serves as an early marker for both metabolic syndrome and atherosclerosis. In the present study, endothelial function was assessed using flow-mediated dilation, a noninvasive ultrasound-based method that measures the ability of a large conduit artery to dilate in response to a shear stress stimulus, or an external force acting on the blood vessel. At the end of the three month treatment period, improved endothelial function was observed in the 300 mg aramchol treated patient group. The table and graph below present the change in endothelial function, as measured by flow mediated dilation observed between baseline and the end-of-treatment for the 48 patients who performed two flow mediated dilation examinations.

Change in Endothelial Function Between Baseline and End Of Treatment

FMD (mm Hg)	Aramchol 300 mg Mean ± SD N = 15	Aramchol 100 mg Mean ± SD N = 15	Placebo Mean ± SD N = 18
Pre-treatment	4.6 ± 2.5	5.4 ± 2.8*	6.4 ± 2.9
Post-treatment	5.9 ± 2.1	5.7 ± 3.9	6.6 ± 2.3
change	1.28 ± 2.92	0.27 ± 3.42	0.23 ± 2.42
P value**	0.4543	0.8979	

N = number of patients

SD = standard deviation

* N = 16 for this data point.

** P value is determined according to an analysis of covariance using the Dunnett method, or a multiple comparison method, for the difference between treatment group and placebo, adjusted for age, gender, diagnosis, baseline HbA1c and baseline weight.

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The improvement in endothelial function suggests a positive effect on metabolic syndrome, specifically on vascular function.

Furthermore, treatment with aramchol was well-tolerated. There were no notable changes in biochemical, hematological, cardiovascular or other safety parameters, and there were no severe drug related adverse events during the three month treatment period or the subsequent recovery period. Aramchol s adverse event profile was comparable to that of the placebo, as portrayed in the chart below.

Phase I Trials

Aramchol was evaluated in two Phase I clinical trials to study its safety, tolerability and PK profile in healthy volunteers, in both single and multiple dose administrations. The first Phase I clinical trial was an escalating single-dose trial conducted in 16 subjects testing single aramchol doses in the range of 30 mg to 900 mg. The subsequent Phase I clinical trial was a repeated-dose trial conducted over four days in 25 subjects testing repeated daily doses of aramchol of 30 mg and 300 mg. The profiles for the groups were similar and the maximal plasma concentration of aramchol increased with the higher doses, as demonstrated in the graph below. The PK profile demonstrated that aramchol is suitable at each dose for once-daily administration and there were neither significant adverse events observed in either Phase I trial nor any notable changes in biochemical, hematologic, cardiovascular or other safety parameters.

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Average Aramchol Plasma Concentration vs. Time Profiles

Additional Preclinical and Clinical Studies Required for Regulatory Submissions

The tolerability of aramchol has been demonstrated in short term preclinical toxicity studies in which no adverse side effects were observed. Additional six month toxicity studies in rats and dogs are ongoing to provide toxicological coverage for long-term clinical studies.

Based on our interactions with the FDA and EMA, we believe that, in addition to the successful completion of the Phase III trials, if initiated in the future, we will need to complete the following preclinical and clinical studies prior to our planned NDA and MAA filings, some of which must be conducted prior to or concurrently with the Phase IIb study:

A six month chronic toxicology study in rats and a nine month chronic toxicology study in dogs, which are currently being conducted to support our planned Phase IIb study. Because existing toxicology studies provide supporting toxicological coverage for studies in humans for three months only, such additional studies are required to extend toxicological coverage to support the Phase IIb study in patients who will receive daily doses of aramchol for one year.

Reproductive studies in rats and rabbits to support our planned Phase III clinical trials. Such reproductive studies are required to minimize the risk of unintentional exposure of the embryo or fetus when including female patients with child-bearing potential in the clinical trials.

Carcinogenicity studies in rats and mice to identify whether aramchol has any tumorigenic potential upon long-term administration in support of any future NDAs or MAAs. Such carcinogenicity studies are required by regulatory agencies for any pharmaceutical that is intended for continuous clinical use for at least six months.

Other supportive studies, including a PK study, a food-effect study and drug-drug interaction study. A PK study will provide information on the absorption, steady state and excretion of the improved formulation of the two doses of aramchol planned for the Phase IIb trial, information which we expect, together with the safety and efficacy data from the Phase IIb trial, will support our future decision regarding the dose to be advanced into pivotal Phase III trials and to the market. A food effect study in humans is necessary to determine the most appropriate dosing information for aramchol in Phase IIb and Phase III clinical trials. The study would indicate whether there are differences in the systemic exposure of aramchol when dosed with food or on an empty stomach. A drug-drug interaction study would monitor the potential interactions of aramchol with other drugs.

Aramchol Formulation Development

There has been a progression of the formulations of aramchol used so far in the preclinical and clinical studies. In the Phase IIa study, we administered a simple compressed tablet form that was developed directly from the suspension used in the Phase Ia and Ib studies and the preclinical studies in animals. However, on further examination, we considered that this was not an ideal formulation due to low absorption rates and high

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individual variability in the Phase IIa PK results. We considered that the low aqueous solubility of aramchol is one factor that might affect the bioavailability, or absorption levels, of aramchol. As part of our ongoing pre-formulation studies, we investigated the solubility in water and simulated gastric and intestinal fluids on aramchol salt forms. The results confirmed that several aramchol salts have improved solubility compared to the existing aramchol free acid form. We have recently submitted new patent applications to protect such salts. In addition, we intend to plan and conduct further animal PK studies in order to test the bioavailability of these salt compounds.

Notwithstanding the foregoing, the optimized conventional tablet for the aramchol free acid form may be suitable for Phase III clinical trial and commercial use, subject to minor alterations for dosage strength after confirmation of the efficacious dose. If we decide to develop the formulations of aramchol salts due to the improvement in solubility and bioavailability and longer patent protection, we may conduct an appropriate bioequivalence, or biological equivalence, of two proprietary preparations of a drug, studies prior to administering an aramchol salt formulation to patients in our clinical studies.

Additional Potential Clinical Indications for Aramchol

Based on the potential fat-reducing effects of aramchol in the liver, we are considering additional indications with meaningful potential market opportunities, with the view of expanding aramchol s therapeutic applications to the treatment of NASH in children, cholesterol gallstones, CASH and feline fatty liver.

Potential Use of Aramchol to Treat NASH in Children

According to the World Health Organization, childhood obesity is one of the most serious public health challenges of the 21st century. The pediatric population is defined in medical literature as the part of the population from birth and up to, but not including, 18 years old. Clinical experience with pediatric NASH is limited. Children are generally diagnosed with NAFLD and/or NASH in the prepubertal age group (generally less than 12 years old but otherwise in the range of four to 16 years old) and are predominantly male. Children of Hispanic origin have a higher incidence of NASH.

Although, as with adult NASH patients, there is no consensus for the treatment of NASH in children, efforts must be made to prevent development of fibrosis, which results in cirrhosis and portal hypertension. Slow, consistent weight loss has been shown to be effective in childhood NAFLD, but as with adults, we believe these lifestyle changes can be difficult to maintain over the long-term. As in adults, several pharmacological agents have been used off-label in children with NASH with varying success.

We intend to prepare a Pediatric Investigational Plan, or PIP, during the first quarter of 2014 in accordance with the European Regulation (EC) No 1901/2006 on medicinal products for pediatric use and a Pediatric Study Plan, or PSP, in accordance with the FDA Safety and Innovation Act. We intend to submit both the PIP and the PSP prior to the end of our adult Phase IIb study.

The PIP and the PSP will likely contain an outline of planned non-clinical juvenile animal studies and pediatric studies, including, to the extent practicable, study objectives and design, age groups, relevant endpoints and statistical approaches. The pediatric population encompasses several subsets defined in international guidelines, including the pre-term and neonate term from zero to 27 days, the infant from one month to 23 months, the child from two years to 11 years and the adolescent from 12 years up to 18 years. The PIP and PSP will consider the relevant age groups for applicability of requests, waivers and deferrals.

We are planning to conduct, but give no assurance that we will conduct or when we will conduct, an open-label Phase I clinical trial of aramchol in children. This trial would be conducted in a small number of healthy children (approximately ten to 15 children), ten years old and older, to ascertain the safety and appropriate dose of aramchol in children. Prior to this study, an animal toxicity study in juvenile animals will likely also be required.

After establishing the safety of aramchol in children, we are planning to conduct, but give no assurance that we will conduct or when we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol in children diagnosed with NASH by NMRS and baseline ALT and AST measurements of at least twice that of normal levels. We plan to administer a pediatric-appropriate dose of aramchol, which is typically

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lower than the doses administered to adults, for six months, followed by a six month post-treatment monitoring period. Our pre-specified criterion for efficacy will be a marked decline in ALT, defined as normalization or greater than 50% of serum ALT levels from baseline, and AST levels, defined as normalization of serum AST levels from baseline, during the treatment period. We will also observe other important liver function markers for positive trends, such as a decrease in cytokeratin levels and an increase in adiponectin levels, during the treatment period. In addition to the proceeds from this offering, additional funding will be required to continue to advance aramchol for this indication. We provide no assurance that we will be able to obtain such funding on favorable terms, if at all.

Potential Use of Aramchol to Treat Cholesterol Gallstones

Cholesterol gallbladder stones, or cholesterol gallstones, are mostly composed of cholesterol, for which bile is the only significant pathway for excretion from the body. Given that phospholipids have been recognized as the major natural cholesterol solubilizers in bile, and which also possess anti-crystallizing activity, we hypothesize that aramchol, which increases the proportion of phospholipids in bile, will be able to prevent or reduce the precipitation of cholesterol gallstones and also clear existing stones. Preliminary *in-vivo* and *in-vitro* studies conducted by the Company have shown that aramchol prevents the formation of cholesterol crystals in the gallbladders of hamsters and mice and is able to dissolve existing cholesterol crystals. The chart below shows that the levels of cholesterol crystallization in human bile is lower after the addition of FABACs to the bile, including aramchol (C-20).

Cholesterol gallstones is a common disorder in the Western world, largely due to dietary and life style factors. According to Schiff s Diseases of the Liver in 2006, gallstones are present in about 10% of the general population, and cholesterol gallstones comprise approximately 80% of such gallstones. In addition, patients who undergo bariatric surgery commonly develop gallstones as a result of such surgery. Almost a quarter of all cholesterol gallstone carriers develop pain as a result of their cholesterol gallstones, as well as complications, and up to half of these carriers eventually undergo surgery to have their cholesterol gallstones removed. Currently, laparoscopic cholecystectomy is the main treatment option for cholesterol gallstones. Surgery is, however, expensive and may cause morbidity and even mortality in high-risk populations, such as the elderly and those with co-morbidities. We expect that the dissolution of cholesterol gallstones using aramchol will only cost a fraction of the price of surgery and will eliminate the mortality and morbidity associated with laparoscopic and open surgery. We also expect aramchol to become an alternative treatment for patients for whom surgery carries a high risk, such as the elderly population, patients with suspected abdominal adhesions and patients with heart, lung or renal problems. Further studies are required to determine whether intermittent maintenance therapy will be required following dissolution of the cholesterol gallstones.

We are planning to conduct, but give no assurance that we will conduct or when we will conduct, an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones. This trial would be conducted over a period of three months in patients with newly formed small cholesterol gallstones after bariatric surgery. The trial would enroll 20 patients to be treated with 600 mg of aramchol

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once-daily. We expect the primary end-points of the trial to be a decrease in the number or size or the complete dissolution of cholesterol gallstones. In addition to the proceeds from this offering, additional funding will be required to continue to advance aramchol for this indication. We provide no assurance that we will be able to obtain such funding on favorable terms, if at all.

We are party to an agreement with Aventis Pharm Deutschland GmbH, or Aventis, which merged with Sanofi S.A. and the company is now called Sanofi S.A., pursuant to which we are obligated to pay Aventis a 10% royalty on sales of aramchol that are indicated for the treatment and prevention of cholesterol gallstones. See Strategic Collaborations, Research Arrangements and Other Material Contracts.

Potential Use of Aramchol to Treat CASH

Preoperative chemotherapy is increasingly used for the treatment of patients with colorectal liver metastases, for which tumor resection is currently the most effective treatment. However, CASH can be a consequence of cancer patients exposure to cytotoxic chemotherapy. After cytotoxic chemotherapy, liver injury is one of the most serious adverse effects of anticancer treatment. It is believed that the progression of fatty liver, or steatosis, to CASH could be due to oxidative stress induced by chemotherapeutic agents. The hepatic injury caused by CASH increases the risk of perioperative morbidity and mortality and also may affect the ability of patients to undergo extended liver resection, particularly those patients who have large tumors or tumors in unfavorable locations, as the excess fat that is present on the liver in CASH can make it difficult for the surgeon seeking to remove the cancer from the liver to see the cancer clearly.

There are no drugs approved by regulatory authorities for the treatment of CASH, although initial studies reported in Expert Opinion on Drug Safety in 2011 (*The role of S-adenosyl methionine in preventing FOLFOX-induced liver toxicity: a retrospective analysis in patients affected by resected colorectal cancer treatment with adjuvant FOLFOX regimen*) have indicated that a drug named S-adenosyl methionine, or AdoMet® (Abbott), may have a protective effect.

In a study conducted by Daniel Keizman, M.D., of the Johns Hopkins University School of Medicine, and Natalie Maimon, M.D., of the Tel Aviv Sourasky Medical Center, aramchol reduced the development of CASH in animal models. In this animal study, conducted in 2009, aramchol significantly decreased the occurrence of CASH in mice treated with oxliplatin, a platinum-based antineoplastic agent that is used in cancer chemotherapy, as demonstrated by the graph below.

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A 35% reduction of liver fat content was observed in the group of chemo-therapy treated mice that were also treated with aramchol. This was caused primarily by a significant reduction of 47% in liver triglyceride content. There were no significant differences noted with regard to animal or liver weights between the groups.

We hypothesize that aramchol will be effective in reducing the formation of liver-fat in the livers of colorectal liver metastases chemotherapy patients by modulating hepatic lipid metabolism and activating the reverse cholesterol transport. In addition to the proceeds from this offering, additional funding will be required to continue to advance aramchol for this indication. We provide no assurance that we will be able to obtain such funding on favorable terms, if at all.

Potential Use of Aramchol to Treat Feline Fatty Liver and as a Preventive Feeding Regimen

According to the Journal of Veterinary Pharmacology and Therapeutics in 2011, feline hepatic lipidosis, or feline fatty liver, has some pathophysiologic similarities to human NAFLD. As such, we believe that aramchol may also be useful in treating feline fatty liver in the same manner that it is able to reduce liver fat in humans, as well as in preventing liver fat accumulation. In our studies, aramchol has shown to reduce liver fat in several animal models, as well as in humans, and is expected to do so in cats as well. There are currently no therapeutic products approved by regulatory authorities for the treatment of feline fatty liver and we are not aware of any other company that is developing a therapeutic for the treatment of feline fatty liver. Therefore, we are currently considering, but provide no assurance that we will pursue, the development of aramchol as a veterinary drug for the treatment of feline fatty liver, as well as a preventive feeding measure for the treatment of obese cats.

According to Veterinary Clinics of North America: Small Animal Practice Journal of 2009, feline fatty liver is the most common form of liver disease diagnosed in cats in North America, and is highly prevalent in Great Britain, Japan and Western Europe. Acute feline fatty liver affects approximately 100,000 cats annually and correlates with obesity in cats. Market analyses conducted by the Company indicate that the market for acute feline fatty liver could be as many as 135,000 cats annually, and that the market for the preventative feeding of obese cats could reach 12.1 million cats annually.

According to Veterinary Clinics of North America: Small Animal Practice, feline fatty liver can develop over the course of a single week of rapid weight loss which could be the result of a number of factors, including unintentional food deprivation, changes in the type of food provided to the cat, sudden changes in lifestyle, stress, or another, unrelated disease. Left untreated, acute feline fatty liver can be fatal, with a mortality rate of approximately 90%. However, when timely diagnosed, feline fatty liver can be cured with an 80% or greater success rate. The only existing therapy is gastrostomy or esophagostomy, which are the surgically administered forced feeding through a feeding tube of protein rich nutrition for a period of three to six weeks, or until voluntary intake of food resumes. The installation of the feeding tube, together with special food requirements and the frequency of feedings, presents a significant financial and time burden on the owner. We believe that the treatment of acute feline fatty liver using aramchol would be less expensive than surgery and that aramchol could also be used as a preventive feeding measure for obese cats to reduce the risk of hepatic fat accumulation, which can lead to feline fatty liver.

A U.S. law, known as the Minor Use and Minor Species Animal Health Act of 2004, or the MUMS Act, aims to make more medications available to treat minor animal species and uncommon diseases in major animal species, and is designed to help pharmaceutical companies overcome the financial roadblocks they face in providing limited-demand animal drugs. With respect to cats, a new product must treat a disease that affects at least 120,000 cats in the United States in order to qualify under the MUMS Act, which is the case with feline fatty liver and obesity in cats. Receipt of

conditional approval for aramchol under the MUMS Act for the treatment of acute feline fatty liver would allow us to sell aramchol for the treatment of acute feline fatty liver before collecting all necessary FDA-required effectiveness data with respect to approval for human use, but rather after proving that aramchol is safe in accordance with the full FDA approval standards and showing that there is a reasonable expectation of effectiveness. Receipt of such conditional approval would also grant us seven years of exclusive marketing rights in the United States, which, similar to an orphan drug designation for humans, means that no other companies can market the same drug in the same dosage for the same intended use during such period. To advance aramchol for the treatment of acute feline fatty liver and as

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a preventative feeding measure for obese cats, we will need to secure funding in addition to the proceeds from this offering. We provide no assurance that we will be able to obtain such funding on favorable terms, if at all.

Potential Future Biomarkers for Non-Invasive Diagnosis of NAFLD and NASH

Currently, the initial diagnosis of NAFLD and/or NASH is based on elevated levels of liver enzymes, such as serum ALT levels, in blood tests. Once further evaluation excludes other reasons for liver disease, such as medications, viral hepatitis or excessive alcohol use, non-invasive imaging tests such as ultrasound, CT scans and NMRS are good indicators of the presence of NAFLD and/or NASH. However, such tests are not reliable in assessing the degree of inflammation and fibrosis which would distinguish between the diseases. Moreover, some of these tests suffer from high rates of false negatives; up to 20% in ultrasound and CT scans. Necroinflammation, or premature cell death coupled with inflammation, hepatocellular ballooning, or a form of liver cell death, and the degree of fibrosis strongly predict the risk of disease progression, all are based on histology. Therefore, the liver biopsy is the standard approach for the diagnosis of inflammation and fibrosis associated with NASH and NAFLD, and the differentiation between them. However, the procedure-related morbidity, pain, sample errors and costs limit its use.

The current lack of specific, non-invasive diagnostic tools for patient monitoring and clinical drug development for NAFLD and NASH presents a major challenge to the scientific and medical communities. Initiation of treatment depends on an accurate diagnosis of NASH, which for now can only be arrived at by biopsy, thus limiting patient care and prognosis. We believe that a non-invasive, reliable diagnostic tool is also needed for the assessment of the efficacy of treatment in a particular patient with NAFLD or NASH, once treatment is initiated.

In light of this unmet need, new non-invasive methods for the diagnosis of NASH have been developed or are currently under development. Among those, NMRS is a validated, commonly used and non-invasive technique for *in-vivo* fat quantification. According to the Journal of Hepatology in 2004, NMRS is routinely used for measuring triglycerides and potentially other liver fat components and is increasingly being used as an endpoint in clinical trials and observational studies, as is the case in our planned Phase IIb aramchol clinical study. If we are successful in our clinical trials in correlating fat reduction in the liver as measured by NMRS with aramchol s effect on inflammation in the liver, NMRS may become a non-invasive biomarker with the ability to measure the effect of aramchol in patients following treatment with the drug.

However, NMRS does not measure inflammation, and thus the need for additional markers must still be addressed. As such, there is currently a growing interest in clinical prediction algorithms and biomarkers, such as the NAFLD fibrosis score, Enhanced Liver Fibrosis panel score and circulating biomarkers, such as CK-18, which is a marker of inflammation.

Recognizing this unmet need, we are collaborating with Enterome Bioscience, a French company, or Enterome, which developed the proprietary EnteroFLTest®, a test seeking to stratify patients according to their bacterial gut composition. By correlating the findings of EnteroFLTest® with liver biopsies in the patients enrolled in our studies, we are working towards finding a specific non-invasive test which would predict individual responses to aramchol, which we believe could increase the likelihood of success of our Phase III trials and facilitate the market adoption of aramchol. On October 30, 2012, we entered into a memorandum of understanding with Enterome with respect to the foregoing. See Strategic Collaborations, Research Agreements and Material Contracts Enterome Bioscience.

We also intend, as part of our Phase IIb study of aramchol, to explore and validate other liver and metabolic biomarkers based on lipidomic profiling of patients treated with aramchol. Lipidomic profiling maps lipid structures,

proteins and genes related to lipid composition in different body components, such as blood and liver tissue. The human body is estimated to contain hundreds or thousands of different lipid species, and each distinct lipid species is thought to have well-defined roles in the maintenance of cellular functions in the human body. The liver is the key organ responsible for metabolism of lipids and lipoproteins, or the lipid carrier particles of blood. Disturbances in hepatic lipid metabolism, such as an increase in lipid accumulation and generation of bioactive lipid species in the liver characteristic of NASH, are reflected in the lipoprotein and lipid content in the liver. As such, we believe that such fluctuations and activity in the liver can be monitored by non-invasive lipidomic profiling. We are collaborating with Zora, a company working on

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lipidomic profiling, in order to identify the lipidomic profile for NASH patients responding to aramchol treatment. On December 19, 2013, we entered into a memorandum of understanding with Zora with respect to the foregoing. See Strategic Collaborations, Research Agreements and Material Contracts Zora Biosciences.

We hope that these efforts will lead to the identification of specific biomarkers, which will differentiate NASH from NAFLD patients without the need for liver biopsy, and serve as a tool for the prediction and assessment of aramchol s efficacy. The identification of such specific biomarkers would greatly improve aramchol s chances of qualifying for reimbursement from third-party payors, by providing an indication of the patients who are most likely to benefit from treatment with aramchol. We do not expect to generate any revenue directly from such biomarkers.

Strategic Collaborations, Research Arrangements and other Material Agreements

Zora Biosciences Oy

On December 19, 2013, we entered into a memorandum of understanding with Zora Biosciences, or the Zora MOU, to explore opportunities to collaborate in order to develop a NASH clinical diagnostic tool, as well as a clinical diagnostic tool for patients receiving aramchol treatment. Zora performs lipidomic profiling analyses in order to generate molecular lipid quantification data.

According to the Zora MOU, in connection with our planned Phase IIb clinical trial of aramchol, we will collect and provide to Zora liver tissue samples from biopsies and serum samples from the patients screened and enrolled in the Israeli-based centers in the trial and Zora will perform lipidomic profiling analysis based on such samples. Once Zora has performed its analysis, Zora is permitted to verify its results by comparing them to the results of the liver biopsies that will be taken from the trial participants and from their MRIs. We expect this to enable Zora to evaluate the performance of its lipidomic profiles and develop a NASH disease clinical diagnostic tool and generate lipidomic profiles correlated with disease progression of patients. We also expect that this will enable Zora to develop a clinical diagnostic tool for patients receiving aramchol treatment, which would be intellectual property owned by us.

We will not receive any financial payment from Zora. However, we will be obligated to pay to-be-agreed upon fees to Zora in respect of its lipidomic analysis activities, and if such activities generate patentable intellectual property for Zora, then we will receive a reimbursement of 40% of such fees.

According to the Zora MOU, we will own all clinical data and Zora will own all lipidomic data, each as generated by our collaboration. We also agreed to grant Zora a free license to use such clinical data only to develop biomarkers and related diagnostics in the field of NASH. Zora will grant to us a free license to use their lipidomic data generated by the clinical trial for developing a clinical diagnostic tool for patients receiving treatment with aramchol. Zora will also grant us a right of first discussion, exercisable upon completion of the Phase IIb clinical trial, to enter into a business transaction with Zora, separate from the transaction and relationship contemplated in the Zora MOU, regarding the commercial exploitation of its NASH disease clinical diagnostic tool based upon the data generated during the collaboration. We agreed to enter into a definitive agreement with Zora on the basis of the principles detailed in the Zora MOU, but no such definitive agreement has been executed as of yet. The Zora MOU is silent as to term, termination and whether or not it is binding.

Guangdong Xianqiang Pharmaceutical Co., Ltd.

On November 27, 2013, we entered into a non-binding memorandum of understanding, or the Xianqiang MOU, with Guangdong Xianqiang Pharmaceutical Co., Ltd., a limited company formed under the laws of the People s Republic of China, or Xianqiang, to explore collaborative opportunities to expand the potential market for aramchol into China.

According to the Xianqiang MOU, we expressed an interest in entering into a definitive agreement with Xianqiang that would grant it an exclusive, non-transferable, non-assignable and non-sublicenseable license to test, manufacture, sell, market and distribute aramchol in China, excluding Hong Kong, Taiwan and Macau, for the treatment of liver diseases only. Such license will be for such period and include such terms and conditions, including royalties, as will be agreed between the parties in such definitive agreement. Pursuant to

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such definitive agreement, all patent applications in connection with aramchol would be filed in our name and Xianqiang would finance all trials, test, clinical studies and other activities necessary to secure marketing approval of aramchol from the relevant regulatory authorities in China for the sale of aramchol in China. Thereafter, Xianqiang would fund the marketing, sales and distribution of aramchol in China. Furthermore, according to the Xianqiang MOU, the parties would agree on a development plan funded by Xianqiang, with Xianqiang owning the results generated in connection with such development plan. The parties agreed to negotiate and execute the relevant definitive agreements within sixty (60) days of entering into the Xianqiang MOU, but no such definitive agreement has been executed as of yet.

Enterome Bioscience

On October 30, 2012, we entered into a memorandum of understanding with Enterome, or the Enterome MOU, to explore opportunities to collaborate in the field of gut microbiota and metabolic disorders by joining our efforts and expertise for the development of biomarkers and patient stratification tools. Enterome develops gut microbiota biomarkers based on quantitative metagenomic analysis for metabolic disorders and immune mediated diseases.

According to the Enterome MOU, in connection with our planned Phase IIb clinical trial of aramchol, Enterome will be permitted to collect stool samples from the patients screened and enrolled in the trial and to perform gut microbiota metagenomic analysis from such samples. Once Enterome has performed its analysis, Enterome is permitted to verify its diagnostic results by comparing them to the results of the liver biopsies that will be taken from the trial participants and from their MRIs. We expect this to enable Enterome to evaluate the performance of its proprietary metagenomic profiles for stratifying patients and to generate metagenomic profiles correlated with patient disease progression. We, in turn, expect to use Enterome s findings to evaluate the correlation between aramchol s dose response data and patient metagenomic profiles in order to stratify potential patients for our future Phase III clinical trials, if any, and to identify NAFLD patients that are at risk of progression to NASH.

We will not receive any financial payment from Enterome and we are not obligated to make any financial payment to Enterome in respect of such activities.

According to the Enterome MOU, we will own all clinical data and Enterome will own all gut microbiota metagenomic data, each as generated by our collaboration. We also agreed to grant Enterome a free license to use such clinical data only to develop biomarkers and related diagnostics to stratify NAFLD patients according to their risk of developing NASH. This license will include the right to use the clinical data associated with the metagenomic data for medical and regulatory development, as well as commercial development. Enterome will grant to us a free license to use their metagenomic data generated by the clinical trial for scientific, clinical and regulatory purposes in developing aramchol, but not for commercial use for developing or promoting a diagnostic product. Enterome will also grant us a right of first refusal, exercisable upon completion of the Phase IIb clinical trial, to enter into a business transaction with Enterome, separate from the transaction and relationship contemplated in the Enterome MOU, regarding the commercial exploitation of its metagenomic profiles and metagenomic data generated during the collaboration. We agreed to enter into a definitive agreement with Enterome on the basis of the principles detailed in the Enterome MOU, but no such definitive agreement has been executed as of yet. The Enterome MOU is silent as to term, termination and whether or not it is binding.

Aventis Pharma Deutschland GmbH

In September 2002, we entered into an agreement, which we refer to as the Aventis Agreement, with Aventis Pharma Deutschland GmbH, or Aventis, which merged with Sanofi S.A. and the company is now called Sanofi S.A., in

connection with the settlement of court proceedings regarding an invention covered by Israeli patent application 123998 and PCT/IL99/00173. The invention relates to certain FABACs, pharmaceutical compositions containing FABACs and the use of FABACs for dissolving cholesterol gallstones in bile and preventing the formation thereof, as well as for the prevention and reduction of atherosclerosis, or the hardening of the arteries. Such court proceedings resulted from a claim filed by us and Prof. Tuvia Gilat, our founder, in the Tel-Aviv District Court seeking a declaratory judgment that Prof. Gilat was the sole inventor of the invention and the owner of all rights in and to the invention and the patent application with respect thereto, and that neither Aventis nor anyone on its behalf has any rights in or to the invention or such

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patent application. We filed the claim with Prof. Gilat based on assertions by Aventis that it had certain rights to the invention as a result of the participation of one of its employees in the discovery of the same. Under the Aventis Agreement, Aventis agreed that we had the exclusive worldwide right to commercialize the invention and we agreed to pay Aventis a royalty of 10% in respect of all income that we or our affiliates may receive from the commercialization of such invention for the prevention and treatment of cholesterol gallstones (less certain standard deductions, including taxes, credits, allowances, rebates, freight and insurance costs), for as long as there is a valid patent or pending patent application covering such invention. Once all valid patents covering the invention expire, and provided that one of Aventis other patents that covers an aspect of the invention is still valid and has received marketing approval prior to the expiration of all the patents covering the invention, the royalty will be reduced to 5%. To date, none of such patents have expired.

The Aventis Agreement does not contain any diligence obligations that require us to exert any special efforts to develop a product for the prevention and treatment of cholesterol gallstones, nor are we contractually required to meet any milestones in respect of the development or commercialization of the invention. We have not yet paid, nor do we currently owe, any amounts to Aventis under the Aventis Agreement.

Unipharm Ltd.

On October 7, 2000, in connection with a certain share subscription agreement, we sent a letter to Unipharm Ltd., or Unipharm, pursuant to which we agreed to negotiate the grant of an exclusive license to Unipharm with respect to the use of patents within our first patent family covering the composition of matter of aramchol within Israel on to-be-agreed upon terms and conditions. The letter stated that, if granted, such license would at all times be subject to our best interests, as determined in our sole discretion, and all approvals and proceedings required by agreement or by law. As of the date hereof, no such definitive agreement has been executed with regard to this matter. The letter is silent as to term, termination and whether or not it is binding. We are currently not in negotiations with Unipharm.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology, intense competition and a highly risky, costly and lengthy research and development process. Adequate protection of intellectual property, successful product development, adequate funding and retention of skilled, experienced and professional personnel are among the many factors critical to success in the pharmaceutical industry.

We believe that aramchol offers key potential advantages over other drugs in development that could enable aramchol, if approved for these indications, to capture meaningful market share. We believe that aramchol s ability, as observed in our studies to date, to reduce liver fat content without adverse side effects, which we believe may prove to have an anti-inflammatory effect, and convenient once-daily oral administration make aramchol a potentially valuable drug for the treatment of liver disease.

Other companies, including Intercept Pharmaceuticals, Inc., Genfit S.A., Gilead Sciences, Inc. and Novo Nordisk have agonists and antibodies in Phase II or earlier stages of clinical development for the treatment of NASH and the fibrosis associated therewith. Antibodies cannot be delivered orally. In addition, Raptor Pharmaceutical Corp. is developing a treatment targeted at NAFLD in children, which may compete with aramchol should we develop and commercialize aramchol for such indication. Some of these companies are focusing their trials on NASH patients with advanced fibrosis, whereas our studies relate to NASH, or the onset of fat accumulation in and inflammation of the liver, in which we expect that aramchol will reduce and eventually eliminate liver inflammation by reducing the fat content of the liver.

We believe that the characteristics of aramchol, as exhibited in our clinical studies to date, including its convenient once-daily oral administration and lack of observable adverse side effects, position it well against the potential competition in the NASH market. Currently used treatments are not approved by applicable regulatory authorities for the indication they are prescribed or used for as they have not proven efficacious in well-designed clinical studies. In addition, drugs in development for the treatment of NASH may, according to published data, be injectable or require intravenous delivery and may cause side effects, such as severe itching, which can be highly inconvenient for patients with chronic diseases, such as NASH, and which may result in low patient compliance.

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Aside from laparoscopic cholecystectomy surgery, the only therapeutic product available for the treatment of cholesterol gallstones is an oral cholesterol gallstone dissolution treatment, and for the prevention of cholesterol gallstones in selected cases, is the bile acid known as ursodeoxycholic acid, both of which have been shown in clinical studies to have low efficacy, slow action and are characterized by cholesterol gallstone recurrence. We are not aware of any other company that has a new product candidate in development for the treatment of cholesterol gallstones. Our preclinical studies demonstrated that aramchol prevents and treats cholesterol gallstones without adverse effects.

Notwithstanding the foregoing, see Risk Factors Risks Related to Our Business, Industry and Regulatory Requirements We might be unable to develop aramchol to achieve commercial success in a timely and cost-effective manner, or ever and Risk Factors Our market is subject to intense competition. If we are unable to compete effectively, aramchol or any other product candidate that we develop may be rendered noncompetitive or obsolete.

Intellectual Property and Patent Strategy

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We own patent rights to aramchol in various jurisdictions worldwide, including within and outside of Israel. We have sought patent protection in the United States and internationally for aramchol and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. We expect that patent protection covering the use of aramchol for the treatment of fatty liver will not expire until 2022 (2021 in Israel), subject to any applicable extensions then-available. Within Israel, we agreed to negotiate the grant of an exclusive license to Unipharm with respect to the use of patents within our first patent family covering the composition of matter of aramchol on to-be-agreed upon terms and conditions. We are not in negotiations with Unipharm and no definitive agreement has been executed as of the date hereof. Within China, excluding Hong Kong, Taiwan and Macau, we have expressed an interest in granting Xianqiang an exclusive license to test, manufacture, sell, market and distribute aramchol for the treatment of liver diseases only on to-be-agreed upon terms and conditions. No definitive agreement has been executed with Xianqiang as of the date hereof. Should we decide to commercialize aramchol for the treatment and prevention of cholesterol gallstones in any country of the world, we will be obligated to pay Aventis a 10% royalty on related sales. See Additional Potential Clinical Indications for Aramchol Potential Use of Aramchol to Treat Cholesterol Gallstones and Strategic Collaborations, Research Arrangements and Other Material Contracts.

Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Patent Portfolio for Aramchol (First-in-Class Synthetic FABAC)

The patent portfolio for aramchol contains patents and pending patent applications directed to composition of matter, manufacturing methods and methods of use. As of October 31, 2013, we own five U.S. patents, two pending U.S. patent applications and corresponding foreign patents and pending patent applications, as detailed below. We have also recently filed priority patent applications for second generation FABAC compounds.

The first patent family discloses and claims FABACs, including aramchol, as well as methods for preventing or dissolving cholesterol gallstones in bile and reducing or preventing arteriosclerosis using FABACs. This patent family includes three issued U.S. patents and an issued European patent that was validated in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland and the United Kingdom. Corresponding patents have been

granted in Australia, Canada, China, Czech Republic, Eurasia, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, Norway, Poland, Turkey and the Ukraine. Foreign patent applications are pending in the Czech Republic and Norway, and patent applications in Brazil and Hungary have been allowed. If the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended patent term for this patent family is due to expire on March 25, 2019, with the exception of the Israeli patent, which is due to expire on April 8, 2018.

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The second patent family discloses and claims additional FABACs with different conjugation moieties, as well as the use of these and the compounds disclosed in the first patent family above, including aramchol, in the treatment of fatty liver, reduction of serum cholesterol and treatment of hyperglycemia and diabetes. This patent family includes a U.S. patent directed to the treatment of fatty liver and a U.S. patent directed to reduction of serum cholesterol by administering additional forms of FABACs. A Continuation-in-Part application is directed to the treatment of a disease or disorder associated with an altered glucose metabolism or insulin action, such as hyperglycemia, diabetes, insulin resistance and obesity. This patent family also includes a European patent that was validated in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom, as well as patents in Australia, Canada, China, Czech Republic, Eurasia, Indonesia, Japan, Korea, Israel, Turkey, Mexico, New Zealand, Norway, Poland and the Ukraine. Foreign patent applications are pending in Hungary, the Czech Republic and Norway. If the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended patent term for this patent family is due to expire on April 15, 2022, with the exception of the Israeli patent, which is due to expire on April 17, 2021. The terms of the U.S. patents in this family have been extended due to patent term adjustments of 567 days for U.S. Patent 7,501,403, which is directed to the treatment of fatty liver, and 24 days for U.S. Patent 8,110,564, which is directed to reduction of serum cholesterol.

A third patent family that is due to expire on February 1, 2030, discloses the use of FABACs in the treatment, prevention and inhibition of progression of Alzheimer's Disease, cerebral amyloid angiopathy and other brain diseases characterized by amyloid plaque deposits. This patent family includes pending patent applications in the United States, Europe and Israel.

A fourth patent family, including two priority patent applications, discloses and claims second generation FABAC compounds.

It is possible that the term of the patents issued in the United States within our first patent family, which includes the composition of matter patents, may be extended up to five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. Patent term extension or supplementary protection certificates may be available in certain foreign countries upon regulatory approval. Independent of patent term extensions, five years of data exclusivity may be provided for this patent in the United States automatically from the day of receiving FDA approval of an NCE in the United States. If the Company pursues commercialization of aramchol in other jurisdictions, longer periods of data exclusivity may pertain.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We believe that our patents provide broad and comprehensive coverage for the use of aramchol for the treatment of certain liver diseases. However, the patent positions of biopharmaceutical companies, such as ourselves, are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for the technology will depend on our success in obtaining effective claims and enforcing those claims once granted. There is no certainty that any of the Company s pending patent applications will result in the issuance of any patents. The issued patents and those that may be issued in the future, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued or future patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time

required for development, testing and regulatory review of a potential product, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of such patent. For more risks associated with the protection of our licensed intellectual property, see Risk Factors Risks Related to Our Intellectual Property.

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Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures 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 or others.

Seasonality

Our business and operations are generally not affected by seasonal fluctuations or factors.

Raw Materials and Suppliers

We believe that the raw materials that we require to manufacture aramchol are readily available commodities commonly used in the pharmaceutical industry. Demand for certain of the required raw materials, such as cholic acid, has recently increased, resulting in a price increase. Although there is no assurance, we anticipate that the price levels of cholic acid will revert back to prior levels and will not experience continued volatility as a result of the entrance of additional manufacturers into the cholic acid market.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, API and finished product for our preclinical research and clinical trials, including the Phase II trials for aramchol for the treatment of NASH. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of our product candidate if it is approved. If our product candidate or future product candidates are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors. The relevant manufacturers of our drug products for our current preclinical and clinical trials have advised us that they are compliant with both current Good Manufacturing Practices, or cGMP, and current Good Laboratory Practices, or cGLP.

There can be no assurance that our product candidate, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs on an ongoing basis, as mandated by the FDA

and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

We currently use Cambridge Major Laboratories, a leading provider of chemistry services to the global pharmaceutical industry, to develop and scale-up a robust manufacturing process to generate up to 40 kg batches of aramchol.

API Scalability Testing

Aramchol is synthesized by conjugating arachidic acid and cholic acid through a chemically stable amide bond. The manufacturing process of aramchol s API has been developed from a laboratory-scaled process up to a full-scaled, commercial manufacturing process. Aramchol s API is manufactured according to cGMP

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process that will be further validated per International Conference on Harmonisation, or ICH, regulations. Stability studies of aramchol conducted on batches used in Phase I and IIa clinical studies confirmed the stability of aramchol s API for up to 24 months at the proposed storage conditions of 25°C at 60% humidity. Additional stability studies are ongoing to ensure appropriate shelf life and storage conditions.

Contract Research Organizations

We outsource certain clinical trial activities, including the administration of treatments, to CROs. Our clinical CROs comply with guidelines from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which attempt to harmonize the FDA and the EMA, regulations and guidelines. We create and implement the drug development plans and manage the CROs according to the specific requirements of the drug candidate under development. To the extent clinical research is conducted by the CROs (or us in the future), compliance with certain federal regulations, including but not limited to 21 C.F.R. parts 50, 54, 56, 58 and 318, which pertain to, among other things, institutional review boards, informed consent, financial conflicts of interest by investigators, good laboratory practices and submitting IND applications, may be required.

Marketing, Sales and Commercialization

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure or capabilities. In the event we receive regulatory approval for aramchol, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market and/or sell our products, if any, through their well-developed sales, marketing and distribution organizations in order to gain access to global markets. In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop. Over the longer term, we may consider ultimately building an internal marketing, sales and commercial infrastructure.

Environmental Matters

We, our agents and our service providers, including our manufacturers, may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities, including, to our knowledge, those of our agents and service providers, are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. All information with respect to any chemical substance is filed and stored as a Material Safety Data Sheet, as required by applicable environmental regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. However, significant expenditures could be required in the future if we, our agents or our service providers are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our

product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the Committee on Human Medicinal Products, or CHMP, via the EMA and European Commission through the MAA process before they may be legally marketed in Europe. Our product candidate and future product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

We are conducting a global development program for aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance, and we may make our submissions for regulatory approval in parallel; initially in Europe and in the United States. Typically, approval time in the United States

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with the FDA for an NDA is faster than that within Europe with the EMA and the European Commission for an MMA, especially when the novelty of the submission is considered. First in class, high medical need and rare disease drugs can experience faster review. Nevertheless, marketing and pricing approval presents a further delay in many countries that should be considered in addition to the regulatory approvals noted above.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, warning letters, product seizures, total or partial suspension of production or distribution, or injunctions, fines, disgorgement, and civil or criminal penalties.

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

completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLPs, or other applicable regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity;

satisfactory completion of FDA inspections of clinical sites and GLP toxicology studies; and

FDA review and approval of the NDA.

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

Once a product candidate is identified for development, it enters the preclinical or nonclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical testing may continue after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a clinical trial protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, due to safety concerns or non-compliance, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. These regulations include the requirement that all research subjects provide informed consent. Further, an IRB

must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information

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regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative and must monitor the study until completed. All clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject inclusion and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report within set timeframes to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

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

Phase II. Clinical trials are performed on a limited patient population intended 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 III. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. Phase III clinical trials are conducted to provide sufficient data for the statistically valid evidence of safety and efficacy.

Human clinical trials are inherently uncertain and Phase I, Phase II and Phase III testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase II and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase II to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support the approval of the NDA. If a Phase II clinical trial is the subject of discussion at the end of Phase II meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor which meets the prerequisites may make a specific request for an SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. There is no indication that we will be able to meet the requirements necessary for an SPA.

Concurrent with clinical trials, sponsors usually complete any remaining animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a

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process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. We will seek a waiver of these fees as a small company submitting its first marketing application. If the waiver is granted it would not extend to establishment or product fees. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Submission of a pediatric assessment is not required for an application to market a product for an orphan-designated indication, and waivers are not needed at this time. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested. The FDA will also inspect selected clinical sites that participated in the clinical studies and may inspect the testing facilities that performed the GLP toxicology studies cited in the NDA.

Expedited Review and Approval

NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA has various specific programs, including Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review, which are each intended to expedite the process for reviewing drugs, and in certain cases involving Accelerated Review, permit approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing

treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs, and Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track, Breakthrough Therapy designation

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and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track or Breakthrough Therapy designated drug and expedite review of the application for a drug designated for priority review. The FDA will also provide Breakthrough Therapy designated drugs intensive guidance on an efficient drug development program and provide these drug developers with an organizational commitment from the FDA involving senior managers. Since sponsors can design clinical trials in a number of ways, in providing its guidance for drugs designated as breakthrough therapies, the FDA will seek to ensure that the sponsor of the product designated as a breakthrough therapy receives timely advice and interactive communications in order to help the sponsor design and conduct a development program as efficiently as possible. During these interactions, the FDA may suggest, or a sponsor can propose, alternative clinical trial designs (e.g., adaptive designs, an enrichment strategy, use of historical controls) that may result in smaller trials or more efficient trials that require less time to complete. Such trial designs could also help minimize the number of patients exposed to a potentially less efficacious treatment (i.e., the control group treated with available therapy). Accelerated Approval, which is described in 21 C.F.R. § 314.500 *et seq*., provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority Review and Accelerated Approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases, subpopulations, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase IV testing, which involves clinical trials designed to further assess a drug s safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

We currently plan to discuss the designation of aramchol as a Breakthrough Therapy or Fast Track development and Accelerated Approval of aramchol for the treatment of NASH at our end-of-Phase II meeting with the FDA, assuming satisfactory achievement, as pre-determined by the FDA, of the surrogate clinical endpoint in our Phase III trials. However, there is no assurance that our product would qualify for any of the streamlined processes or that we would be permitted to use surrogate data. The use of surrogate data is rare and limited.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2)

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NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five year and three year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Post-approval Requirements

Once an approval is granted, the FDA, European authorities and other regulatory authorities may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. 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. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further regulatory authority review and approval. Some of these modifications, especially adding indications, would likely require additional clinical studies. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug product manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things record-keeping requirements; reporting of adverse experiences with the drug; providing the FDA with updated safety and efficacy information; drug sampling and distribution requirements; notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Reimbursement

Sales of our products will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies

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in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The MMA imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D reimbursement is not set by the Government, but rather by private insurers. Moreover, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Recently, the Centers for Medicare & Medicaid Services proposed a rule that would enable Part D plans to offer fewer drugs than would otherwise be the case. The impact of this proposed rule on a product such as ours cannot be predicted at this time, but it could have a material adverse impact on our product were it being marketed at this time. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor s product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Affordable Care Act, enacted in March 2010, is expected to have a significant impact on the health care industry. Affordable Care Act is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, Affordable Care Act is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of Affordable Care Act on pharmaceutical companies. See Risk Factors Risks Related to Our Business, Industry and Regulatory Requirements We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the

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market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

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 Medicare-Medicaid Anti-Fraud and Abuse Act, as amended (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, a similar federal requirement requires 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 federal authorities.

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European Economic Area

In addition to approval in the United States, we currently intend to seek regulatory approval of aramchol in the EU. As such, a summary of the EU regulatory processes follows below.

A medicinal product may only be placed on the market in the European Economic Area, or EEA, composed of the 28 EU member states, plus Norway, Iceland and Lichtenstein, when a marketing authorization has been issued by the competent authority of a member state pursuant to Directive 2001/83/EC (as recently amended by Directive 2004/27/EC), or an authorization has been granted under the centralized procedure in accordance with Regulation (EC) No. 726/2004 or its predecessor, Regulation 2309/93. There are essentially three community procedures created under prevailing European pharmaceutical legislation that, if successfully completed, allow an applicant to place a medicinal product on the market in the EEA.

Centralized Procedure

Regulation 726/2004/EC now governs the centralized procedure when a marketing authorization is granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the EMA. That authorization is valid throughout the entire community and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of a biotechnological process in accordance with Paragraph 1 to the Annex to the Regulation. Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes must also be authorized centrally. Starting on May 20, 2008, the mandatory centralized procedure was extended to autoimmune diseases and other immune dysfunctions and viral diseases. Finally, all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000 must be authorized under the centralized procedure. An applicant may also opt for assessment through the centralized procedure if it can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients at the community level. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application. This 210 days period does not include the time that the applicant to answer any questions raised during the application procedure, the so-called clock stop period. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the draft decision granting a marketing authorization. This draft decision may differ from the CHMP opinion, stating reasons for diverging for the CHMP opinion. The draft decision is sent to the applicant and the member states, after which the European Commission takes a final decision. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. All CHMP refusals and the reasons for refusal are made public on the EMA website. Without a centralized marketing authorization it is prohibited to place a medicinal product that must be authorized centrally on the market in the EU.

Mutual Recognition and Decentralized Procedures

With the exception of products that are authorized centrally, the competent authorities of the member states are responsible for granting marketing authorizations for medicinal products placed on their national markets. If the

applicant for a marketing authorization intends to market the same medicinal product in more than one member state, the applicant may seek an authorization progressively in the community under the mutual recognition or decentralized procedure. Mutual recognition is used if the medicinal product has already been authorized in a member state. In this case, the holder of this marketing authorization requests the member state where the authorization has been granted to act as reference member state by preparing an updated assessment report that is then used to facilitate mutual recognition of the existing authorization in the other member states in which approval is sought (the so-called concerned member state(s)). The reference member state must prepare an updated assessment report within 90 days of receipt of a valid application. This

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report together with the approved Summary of Product Characteristics, or SmPC (which sets out the conditions of use of the product), and a labeling and package leaflet are sent to the concerned member states for their consideration. The concerned member states are required to approve the assessment report, the SmPC and the labeling and package leaflet within 90 days of receipt of these documents. The total procedural time is 180 days.

The decentralized procedure is used in cases where the medicinal product has not received a marketing authorization in the EU at the time of application. The applicant requests a member state of its choice to act as reference member state to prepare an assessment report that is then used to facilitate agreement with the concerned member states and the grant of a national marketing authorization in all of these member states. In this procedure, the reference member state must prepare, for consideration by the concerned member states, the draft assessment report, a draft SmPC and a draft of the labeling and package leaflet within 120 days after receipt of a valid application. As in the case of mutual recognition, the concerned member states are required to approve these documents within 90 days of their receipt.

For both mutual recognition and decentralized procedures, if a concerned member state objects to the grant of a marketing authorization on the grounds of a potential serious risk to public health, it may raise a reasoned objection with the reference member state. The points of disagreement are in the first instance referred to the Co-ordination Group on Mutual Recognition and Decentralized Procedures, or CMD, to reach an agreement within 60 days of the communication of the points of disagreement. If member states fail to reach an agreement, then the matter is referred to the EMA and CHMP for arbitration. The CHMP is required to deliver a reasoned opinion within 60 days of the date on which the matter is referred. The scientific opinion adopted by the CHMP forms the basis for a binding European Commission decision.

Irrespective of whether the medicinal product is assessed centrally, de-centrally or through a process of mutual recognition, the medicinal product must be manufactured in accordance with the principles of good manufacturing practice as set out in Directive 2003/94/EC and Volume 4 of the rules governing medicinal products in the European community. Moreover, community law requires the clinical results in support of clinical safety and efficacy based upon clinical trials conducted in the European community to be in compliance with the requirements of Directive 2001/20/EC, which implements good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the European community and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the community.

National Procedure

This procedure is available for medicinal products that do not fall within the scope of mandatory centralized authorization. Specific procedures and timelines differ between member states, but the duration of the procedure is generally 210 days and based on a risk/efficacy assessment by the competent authority of the member state concerned, followed by determination of SmPC, package leaflet and label text/layout and subsequently grant of the marketing authorization. Marketing authorizations granted on this basis are not mutually recognized by other member states.

There are various types of applications for marketing authorizations:

Full Applications. A full application is one that is made under any of the community procedures described above and stands alone in the sense that it contains all of the particulars and information required by Article 8(3) of Directive 2001/83 (as amended) to allow the competent authority to assess the quality, safety and efficacy of the product and in

particular the balance between benefit and risk. Article 8(3)(l) in particular refers to the need to present the results of the applicant s research on (i) pharmaceutical (physical-chemical, biological or microbiological) tests, (ii) preclinical (toxicological and pharmacological) studies and (iii) clinical trials in humans. The nature of these tests, studies and trials is explained in more

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detail in Annex I to Directive 2001/83/EC. Full applications would be required for products containing new active substances not previously approved by the competent authority, but may also be made for other products.

Abridged Applications. Article 10 of Directive 2001/83/EC contains exemptions from the requirement that the applicant provide the results of its own preclinical and clinical research. There are three regulatory routes for an applicant to seek an exemption from providing such results, namely (i) cross-referral to an innovator s results without consent of the innovator, (ii) well established use according to published literature and (iii) consent to refer to an existing dossier of research results filed by a previous applicant.

Cross-referral to Innovator s Data

Articles 10(1) and 10(2)(b) of Directive 2001/83/EC provide the legal basis for an applicant to seek a marketing authorization on the basis that its product is a generic medicinal product (a copy) of a reference medicinal product that has already been authorized, in accordance with community provisions. A reference product is, in principle, an original product granted an authorization on the basis of a full dossier of particulars and information. This is the main exemption used by generic manufacturers for obtaining a marketing authorization for a copy product. The generic applicant is not required to provide the results of preclinical studies and of clinical trials if its product meets the definition of a generic medicinal product and the applicable regulatory results protection period for the results submitted by the innovator has expired. A generic medicinal product is defined as a medicinal product:

having the same qualitative and quantitative composition in active substance as the reference medicinal product;
having the same pharmaceutical form as the reference medicinal product; and
whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Applications in respect of a generic medicinal product cannot be made before the expiry of the protection period. Where the reference product was granted a national marketing authorization pursuant to an application made before October 30, 2005, the protection period is either six years or 10 years, depending upon the election of the particular member state concerned. Where the reference product was granted a marketing authorization centrally, pursuant to an application made before November 20, 2005, the protection period is 10 years. For applications made after these dates, Regulation 726/2004 and amendments to Directive 2001/83/EC provide for a harmonized protection period regardless of the approval route utilized. The harmonized protection period is in total 10 years, including eight years of research data protection and two years of marketing protection. The effect is that the originator s results can be the subject of a cross-referral application after eight years, but any resulting authorization cannot be exploited for a further two years. The rationale of this procedure is not that the competent authority does not have before it relevant tests and trials upon which to assess the efficacy and safety of the generic product, but that the relevant particulars can, if the research data protection period has expired, be found on the originator s file and used for assessment of the generic medicinal product. The 10 year protection period can be extended to 11 years where, in the first eight years post-authorization, the holder of the authorization obtains approval for a new indication assessed as offering a significant clinical benefit in comparison with existing products.

If the copy product does not meet the definition of a generic medicinal product or if certain types of changes occur in the active substance(s) or in the therapeutic indications, strength, pharmaceutical form or route of administration in relation to the reference medicinal product, Article 10(3) of Directive 2001/83/EC provides that the results of the appropriate preclinical studies or clinical trials must be provided by the applicant.

Well-established Medicinal Use

Under Article 10a of Directive 2001/83/EC, an applicant may, in substitution for the results of its own preclinical and clinical research, present detailed references to published literature demonstrating that the active substance(s) of a product have a well-established medicinal use within the community with recognized efficacy and an acceptable level of safety. The applicant is entitled to refer to a variety of different types of

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literature, including reports of clinical trials with the same active substance(s) and epidemiological studies that indicate that the constituent or constituents of the product have an acceptable safety/efficacy profile for a particular indication. However, use of the published literature exemption is restricted by stating that in no circumstances will constituents be treated as having a well-established use if they have been used for less than 10 years from the first systematic and documented use of the substance as a medicinal product in the EU. Even after 10 years systematic use, the threshold for well-established medicinal use might not be met. European pharmaceutical law requires the competent authorities to consider among other factors the period over which a substance has been used, the amount of patient use of the substance, the degree of scientific interest in the use of the substance (as reflected in the scientific literature) and the coherence (consistency) of all the scientific assessments made in the literature. For this reason, different substances may reach the threshold for well-established use after different periods, but the minimum period is 10 years. If the applicant seeks approval of an entirely new therapeutic use compared with that to which the published literature refers, additional preclinical and/or clinical results would have to be provided.

Informed Consent

Under Article 10c of Directive 2001/83/EC, following the grant of a marketing authorization the holder of such authorization may consent to a competent authority utilizing the pharmaceutical, preclinical and clinical documentation that it submitted to obtain approval for a medicinal product to assess a subsequent application relating to a medicinal product possessing the same qualitative and quantitative composition with respect to the active substances and the same pharmaceutical form.

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) was adopted on December 12, 2006. This Regulation governs the development of medicinal products for human use in order to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a product not authorized in the European Community on January 26, 2007 (the time the Regulation entered into force), to include the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed by the Pediatric Committee of the EMA, unless the product is subject to an agreed waiver or deferral or unless the product is excluded from the scope of Regulation 1902/2006 (generics, hybrid medicinal products, biosimilars, homeopathic and traditional (herbal) medicinal products and medicinal products containing one or more active substances of well-established medicinal use). Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. The EMA does not evaluate an application for market authorization if there is no agreed PIP, deferral or waiver. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a product already authorized and still protected by a supplementary protection certificate granted under Regulation EC 469/2009 and its precursor (EEC) 1768/92 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the product, unless the product is subject to orphan drug designation, in which case the 10 year market exclusivity period for such orphan products is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six month extension of the supplementary protection certificate is only granted if the medicinal product is authorized in all member states.

Post-authorization Obligations

In the pre-authorization phase the applicant must provide a detailed pharmacovigilance plan that it intends to implement post-authorization. An authorization to market a medicinal product in the EU carries with it an obligation to comply with many post-authorization organizational and behavioral regulations relating to the marketing and other activities of authorization holders. These include requirements relating to post-authorization efficacy studies, post-authorization safety studies, adverse event reporting and other pharmacovigilance requirements, advertising, packaging and labeling, patient package leaflets, distribution and

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wholesale dealing. The regulations frequently operate within a criminal law framework and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers. As a result of the currently on-going overhaul of EU pharmacovigilance legislation the financial and organizational burden on market authorization holders will increase significantly, such as the obligation to maintain a pharmacovigilance system master file that applies to all holders of marketing authorizations granted in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. Marketing authorization holders must furthermore collect data on adverse events associated with use of the authorized product outside the scope of the authorization. Pharmacovigilance for biological products and medicines with a new active substance will be strengthened by subjecting their authorization to additional monitoring activities. The EU is currently in the process of issuing implementing regulations for the new pharmacovigilance framework.

Any authorization granted by member state authorities, which within three years of its granting is not followed by the actual placing on the market of the authorized product in the authorizing member state ceases to be valid. When an authorized product previously placed on the market in the authorizing member state is no longer actually present on the market for a period of three consecutive years, the authorization for that product shall cease to be valid. The same two three year periods apply to authorizations granted by the European Commission based on the centralized procedure.

Israel

Clinical Testing in Israel

In order to conduct clinical testing on humans in Israel, special authorization must first be obtained from the ethics committee and general manager of the institution in which the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations also require authorization from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and similar trials, an additional authorization of the overseeing institutional ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. Since we intend to perform a portion of the clinical studies on certain of our therapeutic candidates in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

Israel Ministry of Health

Israel s Ministry of Health, which regulates medical testing, has adopted guidelines that correspond, generally, to those of the FDA and the EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the EMA requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU commercial markets in an expedited fashion. Many members of Israel s medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the EU.

Other Countries

In addition to regulations in the United States, the EU and Israel, we are subject to a variety of other regulations governing clinical trials and commercial sales and distribution of drugs in other countries. Whether or not our product candidate or future product candidates receive approval from the FDA, approval of such product candidates must be obtained by the comparable regulatory authorities of countries other than the United States before we can commence clinical trials or marketing of the product in those countries. The approval process varies from jurisdiction to jurisdiction, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials and product licensing vary greatly from country to country.

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The requirements that we and our collaborators must satisfy to obtain regulatory approval by government agencies in other countries prior to commercialization of our products in such countries can be rigorous, costly and uncertain. In the European countries, Canada and Australia, regulatory requirements and approval processes are similar in principle to those in the United States. Additionally, depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval in the European countries: mutual recognition and the centralized procedure. These review mechanisms may ultimately lead to approval in all EU countries, but each method grants all participating countries some decision-making authority in product approval. Foreign governments also have stringent post-approval requirements including those relating to manufacture, labeling, reporting, record keeping and marketing. Failure to substantially comply with these on-going requirements could lead to government action against the product, us and/or our representatives.

Related Matters

From time to time, legislation is drafted, introduced and passed in governmental bodies that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA or EMA and other applicable regulatory bodies to which we are subject. In addition, regulations and guidance are often revised or reinterpreted by the national agency in ways that may significantly affect our business and our therapeutic candidates. It is impossible to predict whether such legislative changes will be enacted, whether FDA or EMA regulations, guidance or interpretations will change, or what the impact of such changes, if any, may be. We may need to adapt our business and therapeutic candidates and products to changes that occur in the future.

Description of Property and Facilities

Our corporate headquarters are located at 8 Shaul Hamelech Blvd., Amot Hamishpat Bldg., Tel Aviv, Israel, 64733, where we lease and occupy approximately 78 square meters of space. The lease for our office expires in April 2016. The aggregate monthly rental payment, together with the maintenance fees, is approximately $2,542. Our headquarters do not include laboratory or product manufacturing facilities. We believe that our facilities are suitable and adequate for our current needs. However, to address growth in the future, we will need to lease additional space.

Employees

As of December 31, 2011, we had six employees, of which two were full-time employees and four were part-time employees or interns. Five were involved in our product development operations and one served in a general and administrative capacity. All of these employees were located in Israel.

As of December 31, 2012, we had seven employees, of which three were full-time employees and four were part-time employees or consultants. Five of such employees were involved in our product development operations and two served in general and administrative capacities. Five of these employees were located in Israel and two of our research and development employees were located in the United Kingdom. The increase in the number of employees from 2011 to 2012 was the result of an increase in our research and development activities, which required more employees.

As of December 31, 2013, we have ten employees, of which five are full-time employees and five are part-time employees or consultants. Six of such employees are involved in our product development operations and four serve in general and administrative capacities. Eight of our employees are located in Israel and two of our research and development employees are located in the United Kingdom. The increase in the number of employees from 2012 to

date was the result of our growing activity in connection with our clinical studies, drug development operations and business development activities, which require more employees in research and development, as well as in administration and operations. Following the completion of this offering and in connection with our future U.S. clinical trials, we intend to hire a vice president for North America, who we expect will be responsible for, among other things, establishing and building a research and development infrastructure in the United States, including for the Phase III clinical trials, communications with the scientific and medical communities, physicians, third-party payors, future partners and collaborators and investor relations, which we believe may increase our operations and presence within the United States.

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While none of our employees located in Israel are party to any collective bargaining agreements or represented by any labor unions, certain provisions of the Israeli labor laws and certain collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists Associations) are applicable to our employees by order of the Israel Ministry of Economics. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums. We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

Legal Proceedings

We are neither party to any legal or arbitration proceedings, including those relating to bankruptcy, receivership or similar proceedings and those involving any third-party, nor any governmental proceedings pending or known to be contemplated, which may have, or have had in the recent past, significant effects on the company s financial position or profitability.

Historical Background and Corporate Structure

Our Company, Galmed Pharmaceuticals Ltd., was incorporated in Israel on July 31, 2013 as a privately held company. However our business has been operating since 2000 under a different group of companies established in the same year, or the Group. Originally, we operated under the parent company, Galmed Holdings Inc., or GHI, a holdings company incorporated in the British Virgin Islands. GHI held all of the rights in Galmed 2000 Inc., or GTTI, also a holdings company incorporated in the British Virgin Islands. GTTI held all of the rights in Galmed International Limited, or GIL, which was incorporated in Malta, an EU member state (other than one share held by GRD for our benefit). GIL held all of the rights in Galmed Medical Research Ltd., or GMR, an Israeli company. Our intellectual property was held by GIL. The research and development was conducted by GMR as a service to GIL on a cost plus basis. GIL was responsible for all product development.

On February 2, 2014, we underwent a reorganization, or the Reorganization, pursuant to which all of our business (including our intellectual property) was transferred to the Company. The Reorganization was conducted in order to simplify our capital structure, reduce our operating cost and to improve our ability to raise funds. The Group was reorganized by way of share transfers and asset transfers, as follows: First, GHI transferred GTTI s entire share capital to the Company; next, GTTI transferred GIL s entire share capital to the Company; then, GIL transferred and assigned all of its intellectual property to our wholly-owned subsidiary, GRD. Immediately prior to the Reorganization, all our shareholders collectively held 9,739 ordinary shares of GHI. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to all such shareholders ordinary shares of the Company, such that upon the Reorganization all our shareholders collectively held 7,099,731 ordinary shares of the Company, in the same proportion among all shareholders, which reflected a ratio of 729 ordinary shares of the Company for each ordinary share of GHI.

In connection with the Reorganization, we obtained the Tax Pre-Ruling, which includes certain restrictions and limitations, including with respect to the transfer of our intellectual property and our ordinary shares and options during a two year period following the completion of the offering, as more fully described in Taxation Israeli Tax Considerations below. Among other things, the Tax Pre-Ruling requires that as of immediately prior to the completion of the Reorganization, the shareholders, option holders and other rights holders of GHI and Galmed Pharmaceuticals Ltd. be identical, and that their respective holdings in each of GHI and Galmed Pharmaceuticals Ltd. also be identical.

The Reorganization resulted with Galmed Pharmaceuticals Ltd. as the parent company and 100% equity-owner of the following companies, as further described in the scheme below: (i) GRD, which holds all of our intellectual property, including the Company s patent portfolio, (ii) GIL, which currently acts as an agent responsible for managing our patent portfolio, development activity and clinical trials and (iii) GTTI, which is an inactive company that we expect to liquidate at or following the end of 2015. GMR is currently

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wholly owned by GIL and will become an inactive company before the end of 2014. The following is a diagram of our corporate structure following the liquidation of GTTI:

In connection with the Reorganization, we obtained the Tax Pre-Ruling, which includes certain restrictions and limitations, as detailed in Taxation Israeli Tax Considerations below.

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MANAGEMENT

Executive Officers and Directors

Set forth below is information concerning the directors, director nominees, senior management and executive officers of the Company as of February 27, 2014. The business address for each of our directors, senior management and corporate officers is c/o Galmed Pharmaceuticals Ltd., 8 Shaul Hamelech Blvd., Amot Hamishpat Bldg., Tel Aviv, Israel 64733.

Name	Age	Position
Chaim Hurvitz	53	Chairman of the Board, Class III Director
Allen Baharaff	49	Chief Executive Officer, Class II Director
Dr. Maya Halperin	61	Chief Medical Officer, Class I Director
Ray Morris	48	Chief Financial Officer
Dr. Maureen Graham	57	Vice President Regulatory
Dr. Antony Appleyard	39	Vice President Drug Development
William Marth[(1)(2)(3)]	59	Class III Director
Shmuel Nir[(1)(2)(3)]	52	Class II Director
Tali Yaron-Eldar[(1)(2)(3)(4)]	50	Director; External Director Nominee

(1) Designated member of our audit committee, or our Audit Committee, to be established upon the consummation of this offering.

(2) Designated member of our remuneration committee, or our Remuneration Committee, to be established upon the consummation of this offering.

(3) Independent director under applicable Nasdaq Capital Market and SEC rules, as affirmatively determined by our Board.

(4) Proposed to serve as an external director under the Companies Law, subject to approval by our shareholders within three months following the completion of this offering.

Following the completion of this offering we intend to identify and select another external director nominee for shareholder approval at a shareholder meeting to be held within three months following the completion of this offering. Upon such shareholder approval, this external director will become a member of our Audit Committee and Remuneration Committee, at which time Mr. Marth will leave the Audit Committee and the Remuneration Committee.

Backgrounds of Current Executive Officers and Directors

Chaim Hurvitz, our chairman of the Board, joined our Board in 2011. Mr. Hurvitz currently serves as the CEO of CH Health, a private venture capital firm, a position he has held since May 2011. Since October 2011, Mr. Hurvitz has served and continues to serve as a member of the board of directors of Teva Pharmaceuticals Industries Ltd. Previously, he was a member of the senior management of Teva Pharmaceuticals Industries Ltd., serving as the President of Teva International Group from 2002 until 2010, as President and CEO of Teva Pharmaceuticals Europe from 1992 to 1999 and as Vice President Israeli Pharmaceutical Sales from 1999 until 2002. Mr. Hurvitz presently serves as a director of Aposense Ltd., a company specializing in the development of proprietary drug conjugates for approved drug therapies to enhance their effectiveness. He is a member of the management of the Manufacturers Association of Israel and head of its pharmaceutical branch. Mr. Hurvitz holds a Bachelor of Arts degree in political

science and economics from Tel Aviv University, which was awarded in 1985.

Allen Baharaff, our Chief Executive Officer, co-founded the Group in 2000 and served as the Chief Financial Officer of GHI since 2000 and as Chief Executive Officer since January 2012. Prior to which, he held a number of senior executive positions, including a Senior Vice President position at Isramex Projects Ltd., an energy project financing company, and Managing Director of T+M Trusteeship & Management Services (Israel) Ltd., a subsidiary of a Swiss company providing trust and similar services. Since 2001, Mr. Baharaff also serves as a member of the board of directors of the Tel-Aviv Museum of Arts, chairing its educational activities and, since 2005, Mr. Baharaff serves as a Director of the Rubin Museum. Mr. Baharaff holds a Bachelor of Science degree in economics from the London School of Economics,

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University of London and LLB and MA degrees from Cambridge University. Since 1993, Mr. Baharaff has been a member of the Israel Bar Association.

Dr. Maya Halperin, our Chief Medical Officer and a member of our Board since 2011, is a Medical Advisor at CH Health, an Israeli private venture capital company controlled by our Chairman since 2011, prior to which, from 2000 to 2010, Dr. Halperin worked in the pharmaceutical industry as a medical director of Teva Pharmaceutical Industries Ltd. in Israel and in Teva s international group of subsidiaries. Dr. Halperin s experience covers managing clinical trials, as well as medical and ethical aspects of drug marketing. Dr. Halperin holds a Medical Degree from Hadassah Medical School, the Hebrew University, Jerusalem and an M.A. in philosophy from the Tel Aviv University.

William Marth, who will serve as a director as of the completion of the offering, has served as the chairman of the board and president and chief executive officer elect of Albany Molecular Research Inc. since May 2012 and has served as the chairman of the board of directors of Sorrento Therapeutics since January 2014. Previously, Mr. Marth has served as President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. in the Americas from June 2010 to November 2012, prior to which he served as President and Chief Executive Officer of Teva North America from January 2008 to June 2010 and as President and Chief Executive Officer of Teva USA from January 2005 to January 2008. From July 1999 to January 2002, he was the Executive Vice President and Vice President of Sales and Marketing for Teva USA. Prior to joining Teva USA, he held various positions with the Apothecon division of Bristol-Myers Squibb. In February 2008, Mr. Marth was elected Chairman of the Generic Pharmaceutical Association where he is also a member of the executive committee. He is a licensed pharmacist and serves on various boards and committees, including The University of the Sciences in Philadelphia, the American Society for Health-System Pharmacists and the Board of Ambassadors for John Hopkins Project RESTORE. Mr. Marth earned his B.Sc. in pharmacy from the University of Illinois in 1977 and his M.B.A. in 1989 from the Keller Graduate School of Management, DeVry University.

Shmuel Nir, a director since 2007, serves as President and Chief Executive Officer of Tushia Consulting Engineers Ltd., an investment and management services company, and Chairman of the board of directors of Matan Digital Printers Ltd. From March 1998 to January 2008, he served as President and Chief Executive Officer of Macpell Industries Ltd., a leading industrial group. Between January 1991 and March 1998, Mr. Nir was an Executive Vice President of Operations at Macpell Industries Ltd. and President and Chief Executive Officer of two of its subsidiaries, New Net Industries Ltd. and New Net Assets Ltd. Prior to January 1991, Mr. Nir had held various positions with Intel Corporation in Jerusalem, Israel and Tefen Management Consulting. Between 1999 and 2006, Mr. Nir served as managing partner at Spring Venture Capital Fund. Mr. Nir holds a B.Sc. in Industrial Engineering and Management from the Technion Israel Institute of Technology in Haifa, which was awarded in 1989.

Tali Yaron-Eldar, who will serve as a director as of the completion of the offering and as an external director nominee under Israeli law, subject to approval by our shareholders within three months after consummation of this offering, is an Israeli attorney specializing in taxation. Ms. Yaron-Eldar co-founded Yaron-Eldar, Paller, Schwartz & Co., Law Offices, in January 2013. Prior to January 2013, she was a partner at the law firm of Tadmor & Co. from March 2007 until December 2012 and a partner at the law firm of Cohen, Yaron-Eldar & Co. from 2004 until March 2007. From January 2004 until January 2008, Ms. Yaron-Eldar served as the Chief Executive Officer of Arazim Investment Company and she has also served in a variety of public positions, including as the Chief Legal Advisor of the Customs and V.A.T department of the Finance Ministry of the State of Israel from 1998 to 2001 and as the Commissioner of Income Tax and Real Property Tax Authority of the State of Israel from 2002 to 2004. Ms. Yaron-Eldar also serves as a director of a number of public companies, including Alliance Tire Company Ltd., Rossetta Genomics Ltd., Medtechnica Ltd., Magicjack Vocaltec Ltd., Lodgia Rotex Investments Ltd. and Tadea Technological Development and Automation Ltd. Ms. Yaron-Eldar holds an M.B.A. specializing in finance from Tel Aviv University which was awarded in 1995 and an LL.B. from Tel Aviv University which was awarded in 1987. Ms. Yaron-Eldar is also a

member of the Israeli Bar Association.

Dr. Maureen Graham, our Vice President Regulatory, has served in such capacity since 2012. Dr. Graham has over 25 years of experience within the pharmaceutical industry and has worked for several

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different companies, including GlaxoSmithKline from 1982 to 1985, Merck & Co from 1985 to 1994, IVAX Pharmaceuticals, Inc. from 1994 to 1998 and Amgen Inc. from 1998 to 2004. She has held a number of directorships, including within Niche Generics Limited, where she served from 2004 to 2005, and has served as the European Director of Regulatory Affairs at Amgen. Dr. Graham founded, and is the managing director of, Diamond BioPharm Limited in 2005, which is a leading technical and scientific consulting group of companies serving the biotechnology and pharmaceutical industry. Dr. Graham has direct experience with many types of products, including biotechnology, gene-therapy, new chemical entities and generics as well as experience and expertise in regulatory and product development issues associated with medicinal products for rare indications. Her extensive experience covers products at all stages of development ranging from preclinical to registration. Dr. Graham is a pharmacist by trade with a Ph.D. in Pharmaceutical Sciences from De Montfort University, Leicester, United Kingdom, which was awarded in 1983, and a Diploma in Regulatory Affairs from Cardiff University, Cardiff, Wales, United Kingdom, which was awarded in 2001.

Ray Morris, our Chief Financial Officer, joined us in such capacity in 2013. Mr. Morris has served in various senior positions at large companies, including as Vice President of Finance and Operations at various portfolio companies of the Infinity Venture Group, a privately-owned business and investment venture holding company, from 2007 to the present. Prior to 2007, Mr. Morris served as Vice President of Finance at Elam EL Industries Ltd., producer of electroluminescent lighting, and its United States, Hong Kong and British Virgin Islands subsidiaries from 1997 until 2006, and as Vice President of Finance at Compubyte Computers (1986) Ltd. from 1994 to 1997. Mr. Morris has also served and continues to serve as a director of several companies, including Mango DSP, Inc., from 2007 to date, and Mate Intelligent Video 2009 Ltd., from 2009 to date. Mr. Morris holds a Bachelor of Science degree in Accounting from Northeastern Illinois University, which was awarded in 1988.

Dr. Antony Appleyard, our Vice President Drug Development and head of chemistry manufacturing and controls, or CMC, is also currently a CMC senior consultant at Diamond BioPharm Ltd., providing product development, regulatory and project management services with over 15 years of experience in research and development, drug discovery, drug delivery, new chemical entities, biologics, formulation, manufacturing and technology transfer. Prior to joining the Company, Dr. Appleyard was an Associate Director of Natural Products Chemistry at Novacta Biosystems Ltd, or Novacta, from 2009 to 2011 and at Cantab Biopharmaceuticals Ltd from 2012 to 2013 where he also held the development positions of CMC Lead and Head of Analysis for development programs. Prior to Novacta, from 2003 to 2004, Dr. Appleyard was engaged in international technology transfer activities for MAb processes at Abbott Laboratories in Dartford, England. He was awarded a degree in chemistry with honors in 1995 and a Ph.D. in biochemistry in 2001, both from the University of Leeds. From 2001 to 2003, Dr. Appleyard carried out post-doctoral research in the Departments of Chemistry and Biochemistry at the University of Cambridge. He is a Fellow of The Royal Society of Chemistry and a Chartered Chemist.

There are no family relationships between any director or executive officer. As of the date hereof, the size and composition of our and GMR s respective boards of directors were originally determined pursuant to a certain shareholders rights agreement, dated December 21, 2011, which was replaced by a new shareholders rights agreement entered into on December 30, 2013 on substantially the same terms. See Certain Relationships and Related Party Transactions Shareholders Rights Agreement. In addition, Mr. Hurvitz was appointed as our Chairman pursuant the provisions of the Convertible Loan Agreement. However, as the Convertible Loan Agreement has terminated and the Shareholders Rights Agreement will terminate upon the consummation of this offering, there will thereafter be no arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any director or executive officer was selected as a director or member of senior management, as the case may be.

Basic Research Scientific Advisory Board and Clinical Advisory Board

We seek advice from our Basic Research Scientific Advisory Board and our Clinical Advisory Board on scientific and medical matters generally. Our Basic Research Scientific Advisory Board includes: Professor Zamir Halpern, from the Gastroenterology Institute of the Tel Aviv Sourasky Medical Center (Ichilov) in Tel Aviv, Israel; Prof. Fred Konikoff, Head of the Department of Gastroenterology and Hepatology at Meir Medical Center in Kfar Saba, Israel; Professor Kenichi Ikejima from Juntendo University in Tokyo, Japan; Dr. P. Jane Armstrong from the College of Veterinary Medicine at the University of Minnesota in

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Minneapolis, Minnesota, and who is also a member of the WSAVA Liver Study Group; Prof. Albert K. Groen from the University of Groningen in Groningen, Netherlands; and Prof. Paolo Parini from the department of Laboratory Medicine at the Karolinska Institute in Stockholm, Sweden. Our Clinical Advisory Board includes Professor Vlad Ratziu, from the University Pierre et Marie Curie in Paris, France and coordinator of the EU FP7 FLIP consortium; Professor Arun Sanyal, from the Virginia Commonwealth University in Richmond, Virginia; Dr. Rohit Loomba, from the University of California San Diego School of Medicine in San Diego, California; Professor Ran Oren from Hadassah University Hospital in Ein Kerem, Jerusalem, Israel and Professor Kenichi Ikejima from Juntendo University in Tokyo, Japan.

We have entered into an Advisory Board Consulting Agreement with each of Professors Vlad Ratziu, Fred Konikoff, Kenichi Ikejima, Dr. P. Jane Armstrong, Prof. Zamir Halpern, Prof. Albert K. Groen, Dr. Rohit Loomba and Prof. Paolo Parini. Each such agreement provides that either party may terminate the agreement upon 30 days prior written notice and contains customary confidentiality, non-solicitation and assignment of inventions provisions. Pursuant to such agreements, and with respect to Professor Ikejima, certain correspondence, we pay each member either a fee ranging from $3,000 per day to approximately $3,375 per day (based on an exchange rate of $1.35 U.S. dollar per Euro) or grant options to purchase our ordinary shares ranging from 60 to 112 ordinary shares under their respective consulting agreements and from 43,740 to 81,648 ordinary shares under their respective option agreements under our 2013 Plan, which are subject to the vesting schedule and other terms and conditions set forth in our 2013 Plan and the respective option agreements. The exercise price of such options ranges from $0.38 to $3.57 per share.

Board Practices

We are incorporated in Israel, and, therefore, we are subject to various corporate governance practices under Israeli law relating to such matters as external directors, independent directors, audit committee, compensation committee and internal auditors. These Israeli law requirements are in addition to the requirements of the Listing Rules of the Nasdaq Capital Market and other relevant provisions of U.S. securities laws. Under such Listing Rules, a foreign private issuer may generally follow its home country practices for corporate governance in lieu of such comparable Listing Rules requirements, except for certain matters such as composition and responsibilities of the audit committee and the SEC-mandated standards for the independence of its members. See below under Nasdaq Capital Market Listing Rules and Home Country Practices for further information.

Membership of the Board

Under our Articles, the Board consists of three classes of directors (not including the two external directors, each of whom are not part of any class) which are appointed for fixed terms of office in accordance with the Companies Law and our Articles, with one class being elected each year for a term of approximately three years by our shareholders at our annual general meeting.

Directors so elected cannot be removed from office by the shareholders until the expiration of their term of office. The directors do not receive any benefits upon the expiration of their term of office.

The three classes of directors are Class I Directors, Class II Directors and Class III Directors. The term of the initial Class I Directors will expire at the annual general meeting of shareholders to be held in 2015; the term of the initial Class II Directors will expire at the annual general meeting of shareholders to be held in 2016; and the term of the initial Class III Directors will expire at the annual general meeting of shareholders to be held in 2017. Dr. Halperin is the initial Class I Director; Mr. Shmuel Nir and Mr. Allen Baharaff are the initial Class II Directors; and Mr. William Marth and Mr. Chaim Hurvitz are the initial Class III Directors. In accordance with the Articles, any vacancies on the

Board of, including unfilled positions, may be filled by a vote of a majority of the directors then in office, and each director chosen in this manner would hold office until the next annual general meeting of the Company (or until the earlier termination of his or her appointment as provided for in the Companies Law or the Articles).

The Articles provide that the minimum number of members of the Board is three and the maximum number is eleven. The Board presently comprises six members but, within three months following the consummation of this offering, is expected to comprise seven members, one of whom is designated as an external director nominee and another who will be designated as the second external director nominee, each to

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be elected at the upcoming general meeting of shareholders to be held within three months following the consummation of this offering pursuant to the provisions of the Companies Law (as discussed below).

A nominee for service as a director in a public company may not be elected without submitting a declaration to the company, prior to election, specifying that he or she has the requisite qualifications to serve as a director, independent director or external director, as applicable, and the ability to devote the appropriate time to performing his or her duties as such.

A director, including an external director or an independent director, who ceases to meet the statutory requirements to serve as a director, external director or independent director, as applicable, must notify the company to that effect immediately and his or her service as a director will expire upon submission of such notice.

External Directors & Financial Experts

Under the Companies Law and the regulations promulgated pursuant thereto, Israeli companies whose shares have been offered to the public, or that are publicly traded outside of Israel, which we refer to as a public company, are required to appoint at least two natural persons as external directors. No person may be appointed as an external director if such person is a relative of a controlling shareholder or if such person, a relative, partner or employer of such person, or anyone to whom such person is directly or indirectly subordinate, or any entity under such person s control, has or had, on or within the two years preceding the date of such person s appointment to serve as an external director, any affiliation with the company to whose board of directors the external director is proposed to be appointed, with any controlling shareholder of the company, with a relative of such controlling shareholder, or with any entity controlled by the company or by a controlling shareholder of the company, or, if the company has no controlling shareholder or a shareholder holding 25% or more of the company s voting rights, any affiliation, at the time of the appointment, to the chairman of the board of directors, the chief executive officer or the most senior financial officer of the company, or to a shareholder holding 5% or more of the outstanding shares or voting rights of the company. The term affiliation includes an employment relationship, a business or professional relationship maintained on a regular basis or control, as well as service as an office holder (as such term is defined in the Companies Law and which term includes a director), except for a term of a director appointed in order to serve as an external director of a company that is about to offer its shares to the public for the first time. The Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine that certain matters will not constitute an affiliation, and has issued certain regulations with respect thereof.

In addition, no person may serve as an external director if: (i) the person s other positions or other business activities create, or may create, a conflict of interest with the person s service as an external director or interfere with the person s ability to serve as an external director; (ii) at the time such person serves as a non-external director of another company on whose board of directors a director of the reciprocal company serves as an external director; (iii) the person is an employee of the Israel Securities Authority or of an Israeli stock exchange; (iv) such person or such person s relative, partner, employer or anyone to whom such person is directly or indirectly subordinate, or any entity under such person s control, has business or professional relations with any person or entity he or she should not be affiliated with, as described in the previous paragraph, unless such relations are negligible; or (v) such person received compensation, directly or indirectly, in connection with such person s services as an external director, other than as permitted under the Companies Law and the regulations promulgated thereunder. If, at the time of election of an external director, all other directors who are not controlling shareholders of such company or their relatives, are of the same gender, then the designated external director must be of the other gender.

Pursuant to the Companies Law, an external director is required to have either financial and accounting expertise or

professional qualifications according to criteria set forth in regulations promulgated under the Companies Law, provided that at least one of the external directors has financial and accounting expertise. The board of directors must make the determination as to the financial and accounting expertise, and as to the professional qualifications, of a director taking into consideration those criteria and matters set forth in the regulations. In addition, the boards of directors of public companies are required to make a determination as to the minimum number of directors who must have such financial and accounting expertise based on, among other things, the type of company, its size, the volume and complexity of the company s activities and the

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number of directors. The Board has determined that the minimum number of directors with financial and accounting expertise, in addition to the external director or directors who have such expertise, will be one, and that Mr. Marth qualifies as such. The external director designee who qualifies to have such expertise is Ms. Yaron-Eldar. Each of Ms. Yaron-Eldar and Mr. Marth also qualifies as an audit committee financial expert pursuant to the applicable SEC rules, and accordingly as having the necessary financial sophistication as required by the Nasdaq Capital Market rules.

External directors are elected for a term of three years at the general meeting of shareholders by a simple majority, provided that the majority includes at least a majority of the shareholders who are not controlling shareholders and who do not have a personal interest in the matter as a result of an affiliation with a controlling shareholder, who are present and voting (abstentions are disregarded), or that the non-controlling shareholders or shareholders who do not have a personal interest in the matter as a result of an affiliation with a controlling shareholder who are present and voted against the election hold 2% or less of the voting power of the company.

External directors may be re-elected for two additional terms of three years each, provided that with respect to the appointment for each such additional three year term, one of the following has occurred: (i) the reappointment of the external director has been proposed by one or more shareholders holding together 1% or more of the aggregate voting rights in the company and the appointment was approved at the general meeting of the shareholders by a simple majority, provided that: (1)(x) in calculating the majority, votes of controlling shareholders or shareholders having a personal interest in the appointment as a result of a relationship with a controlling shareholder and abstentions are disregarded and (y) the total number of shares of shareholders who do not have a personal interest in the appointment as a result of a relationship with a controlling shareholder and/or who are not controlling shareholders, present and voting in favor of the appointment exceed 2% of the aggregate voting rights in the company, and (2) the external director so reappointed is not a related or competing shareholder, or a relative of such shareholder, at the time of the appointment, and does not and did not have, any affiliation with a related or competing shareholder, on or within the two years preceding such person s reappointment to serve as another term as external director. The term related or competing shareholder means the shareholder(s) proposing the reappointment or a shareholder holding 5% or more of the outstanding shares or voting rights of the company, provided that at the time of the reappointment, such shareholder(s), a controlling shareholder of such shareholder(s), or a company controlled by such shareholder(s), have a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine that certain matters, under his conditions, will not constitute a business relationship or competition with the company; or (ii) the reappointment of the external director has been proposed by the board of directors and the appointment was approved by the majority of shareholders required for the initial appointment of an external director.

However, under regulations promulgated pursuant to the Companies Law, companies whose shares are listed for trading on specified exchanges outside of Israel, including the Nasdaq Capital Market, may elect external directors for additional terms that do not exceed three years each, beyond the three three year terms generally applicable, provided that, if an external director is being re-elected for an additional term or terms beyond three three year terms: (i) the audit committee and board of directors must determine that, in light of the external director s expertise and special contribution to the board of directors and its committees, the re-election for an additional term is to the company s benefit; (ii) the external director must be re-elected by the required majority of shareholders as described above; and (iii) the term during which the nominee has served as an external director and the reasons given by the audit committee and board of directors for extending his or her term of office must be presented to the shareholders prior to their approval.

Following termination of service as an external director, a public company, a controlling shareholder thereof and any entity controlled by a controlling shareholder, may not grant any benefit, directly or indirectly, to any person who served as an external director of such public company, or to his or her spouse or child, including, not appointing such

person, or his or her spouse or child, as an office holder of such public company or of any entity controlled by a controlling shareholder of such public company, not employing such person or his or her spouse or child and not receiving professional services for pay from such person, either directly or indirectly, including through a corporation controlled by such person, all until the lapse of

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two years from termination of office with respect to the external director, his or her spouse or child; and until the lapse of one year from termination of office with respect to other relatives of the former external director.

Each committee of the Board that is authorized to exercise powers of a company's board of directors must include at least one external director. The audit and remuneration committees of a company s board of directors must include all of such company s external directors.

Under the Companies Law, an external director cannot be dismissed from office unless: (i) the board of directors determines that the external director no longer meets the statutory requirements for holding the office, or that the external director is in breach of his or her duty of loyalty to the company and the shareholders vote, by the same majority required for the appointment, to remove the external director after the external director has been given the opportunity to present his or her position; (ii) a court determines, upon a request of a director or a shareholder, to dismiss the external director after finding that such external director no longer meets the statutory requirements of an external director or that the external director is in breach of his or her duty of loyalty to the company; or (iii) a court determines, upon a request of the company or a director, shareholder or creditor of the company, to dismiss the external director after finding that such external director is unable to fulfill his or her duty or has been convicted of specified crimes.

Ms. Yaron-Eldar is the current external director designee and was appointed to our Board to serve as such. Following the completion of this offering we will identify and select another external director nominee, who along with Ms. Yaron-Eldar, will be presented for shareholder approval at a shareholder meeting to be held within three months following the completion of this offering. Each of the nominees for external director, upon election by the shareholders, will serve for an initial term of three years.

Independent Directors Under the Companies Law

Under the Companies Law an independent director is either an external director or a director appointed or classified as such who meets the same non-affiliation criteria as an external director, as determined by the audit committee, and who has not served as a director of the company for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director s service. An independent director may be removed from office in the same manner that an external director may be removed and, upon termination of service as an independent director, is subject to the same restrictions with respect to receipt of benefits, service as an office holder, employment and provision of professional services as are applicable to external directors.

Pursuant to the Companies Law, a public company, such as the Company, may include in its articles of association a provision providing that a specified number of its directors be independent directors or may adopt a standard provision providing that a majority of its directors be independent directors or, if there is a controlling shareholder or a shareholder holding 25% or more of the company s share capital, that at least one-third of its directors be independent directors.

Regulations promulgated pursuant to the Companies Law provide that a director in a public company whose shares are listed for trading on specified exchanges outside of Israel, including the Nasdaq Capital Market, such as the Company, who qualifies as an independent director under the relevant non-Israeli rules relating to independence standards for audit committee membership and who meets certain non-affiliation criteria, which are less stringent than those applicable to external directors, would be deemed an independent director pursuant to the Companies Law provided (i) he or she has not served as a director for more than nine consecutive years; (ii) he or she has been

approved as such by the audit committee; and (iii) his or her remuneration shall be in accordance with the Israeli regulations promulgated pursuant to the Companies Law governing the terms of compensation payable to external directors, or the Compensation Regulations. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service.

Furthermore, pursuant to these regulations, such company may reappoint a person as an independent director for additional terms, beyond nine years, which do not exceed three years each, if the audit committee

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and the board of directors determine that in light of the independent director s expertise and special contribution to the board of directors and its committees, the reappointment for an additional term is to the company s benefit.

Alternate Directors

Our Articles provide that a director may, by written notice to the Company, appoint another person to serve as an alternate director provided that such appointment is approved by a majority of the directors then in office, and that such appointing director may remove such alternate director. Any alternate director shall be entitled to notice of meetings of the Board and of relevant committees and to attend and vote accordingly, except that the alternate has no standing at any meeting at which the appointing director is present or at which the appointing director is not entitled to participate as provided in the Companies Law. A person who is not qualified to be appointed as a director, or a person who already serves as a director or an alternate director, may not be appointed as an alternate director.

Unless the appointing director limits the time or scope of the appointment, the appointment is effective for all purposes until the earlier of (i) the appointing director ceasing to be a director; (ii) the appointing director terminating the appointment; or (iii) the occurrence, with respect to the alternate, of any of the circumstances under which a director shall vacate his or her office. The appointment of an alternate director does not in itself diminish the responsibility of the appointing director, as a director. An alternate director is solely responsible for his or her actions and omissions and is not deemed an agent of the appointing director. Under the Companies Law, external directors cannot generally appoint alternate directors, and a person who is not qualified to be appointed as an independent director may not be appointed as an alternate to an independent director. See Membership of Board, External Directors & Financial Experts, and Independent Directors above. At present, there are no effective appointments of alternate directors for our Board.

Our Articles also provide that the Board may delegate any, or all, of its powers to one or more committees of the Board, and may entrust to and confer upon a managing director such of its powers as it deems appropriate. However, the Companies Law provides that certain powers and authorities (for example, the power to approve the financial statements) may not be delegated and may be exercised only by the Board. Notwithstanding the foregoing, we intend to comply with the corporate governance requirements of the Nasdaq Capital Market, except to the extent indicated elsewhere in this prospectus, including as set forth under Nasdaq Capital Market Listing Rules and Home Country Practices below.

Committees of the Board

Audit Committee

The Companies Law requires public companies to appoint an audit committee comprised of at least three directors, including all of the external directors, the majority of whom must be independent directors under the Companies Law. The Companies Law further stipulates that the following may not be members of the audit committee: (i) the chairman of the board of directors; (ii) any director employed by or providing services on an ongoing basis to the company, to a controlling shareholder of the company or an entity controlled by a controlling shareholder of the company; (iii) a director whose livelihood depends on a controlling shareholder; and (iv) a controlling shareholder or any relative of a controlling shareholder.

The Companies Law further requires that: (i) the chairperson of the audit committee must be an external director; (ii) generally, any person who is not entitled to be a member of the audit committee may not attend the audit committee s meetings and voting sessions, unless such person was invited by the chairperson of the committee for the purpose of

presenting a specific subject matter thereof; and (iii) the quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee be a majority of the members of the audit committee, provided that the majority of the members present are independent directors and at least one of them is an external director.

The responsibilities of the audit committee under the Companies Law include: (i) identifying flaws in the management of a company's business and making recommendations to the board of directors as to how to correct them; (ii) with respect to certain actions involving conflicts of interest and with respect to certain

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related party transactions, deciding whether such actions are material actions and whether such transactions are extraordinary transactions, respectively, all for the purpose of approving such actions or transactions; (iii) reviewing and deciding whether to approve certain related party transactions and certain actions involving conflicts of interest; (iv) reviewing the internal auditor's work program; (v) examining the company's internal control structure and processes, the performance of the internal auditor and whether the internal auditor has at his or her disposal the tools and resources required to perform his or her duties, considering, inter alia, the special needs of the company and its size; (vi) examining the external auditor's scope of work as well as the external auditor's fees and providing its recommendations to the appropriate corporate organ; (vii) providing for arrangements as to the manner in which the company will deal with employee complaints with respect to deficiencies in the management of the company's business and the protection to be provided to such employees; and (viii) with respect to related party transactions with a controlling shareholder, regardless of whether such transactions are extraordinary transactions, that prior to entering into such transaction, to establish the requirement of having a competitive process under the supervision of the audit committee or any individual, committee or body on its behalf and according to criteria established by the audit committee and to determine procedures for approving certain related party transactions with a controlling shareholder, which were determined by the audit committee to be non-extraordinary transactions, but which are not negligible transactions.

Mr. Nir, Ms. Yaron-Eldar and Mr. Marth are the currently designated members of our Audit Committee. Each of them is an independent director in accordance with the Nasdaq Capital Market corporate governance requirements, as affirmatively determined by our Board, and Ms. Yaron-Eldar also meets the qualifications for service as an external director under the Companies Law and the regulations promulgated thereunder, also as affirmatively determined by our Board. Upon approval of Ms. Yaron-Eldar and the additional nominee as external directors within three months following the completion of this offering, each of Ms. Yaron-Eldar and such external director will become a member of the Audit Committee, at which time Mr. Marth will leave the Audit Committee. In addition, our Board has affirmatively determined that Ms. Yaron-Eldar also qualifies as an audit committee financial expert pursuant to the applicable SEC rules, and accordingly as having the necessary financial sophistication as required by the Nasdaq Capital Market rules, and as a financial and accounting expert under the Companies Law.

Our Board 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 Capital Market, as well as the requirements for such committee under the Companies Law, as described below.

Our Audit Committee will oversee the accounting and financial reporting processes of the Company. It will also provide assistance to the Board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, auditing, financial reporting and internal control functions of the Company. In carrying out its duties, our Audit Committee will meet with management at least once in each fiscal quarter at which time, among other things, it will review, and either approves or disapproves, the financial results of the Company for the immediately preceding fiscal quarter and will convey its conclusions in this regard to the Board. Our Audit Committee will also monitor generally the services provided by the Company s external auditors to ensure their independence, and will review all audit and non-audit services provided by them. The Company s external and internal auditors will also report regularly to our Audit Committee at its meetings, and our Audit Committee will discuss with the Company s external auditors the quality, not just the acceptability, of the accounting principles, the reasonableness of significant judgments and the clarity of disclosures in the Company s financial statements, as and when it deems it appropriate to do so.

Under the provisions of the Sarbanes-Oxley Act, the audit committee is directly responsible for the appointment, compensation and oversight of the work of the company s external auditors. However, under Israeli law, the appointment of external auditors and their compensation require the approval of the shareholders of a public company. Pursuant to Israeli law, the shareholders may delegate the authority to determine the compensation of the external

auditors to the board of directors. In addition, pursuant to the Companies Law, the audit committee is required to examine the external auditors fees and to provide its recommendations with respect thereto to the appropriate corporate organ. Accordingly, the appointment of the external auditors will be required to be approved and recommended to the shareholders by our Audit Committee and approved by the shareholders. The compensation of the external auditors will be required to

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be approved by our Audit Committee and recommended to the shareholders or, if so authorized by the shareholders, to the Board and approved by either the shareholders or the Board, as the case may be.

Remuneration Committee

The Companies Law requires public companies to appoint a remuneration committee comprised of at least three directors, including all of the external directors, who must generally also constitute a majority of the members. All other members of the committee, who are not external directors, must be directors who receive compensation consistent with that of external directors and that is in compliance with the Compensation Regulations. In addition, the chairperson of the remuneration committee must be an external director.

The Companies Law further stipulates that directors who are not qualified to serve on the audit committee, as described above, may not serve on the remuneration committee either and that similar to the audit committee, generally, any person who is not entitled to be a member of the remuneration committee may not attend the remuneration committee s meetings. Our Board has adopted a remuneration committee charter setting forth the responsibilities of our Remuneration Committee, as described below.

The responsibilities of the remuneration committee under the Companies Law include: (i) making recommendations to the board of directors with respect to the approval of the compensation policy and any extensions thereto; (ii) periodically reviewing the implementation of the compensation policy and providing the board of directors with recommendations with respect to any amendments or updates thereto; (iii) reviewing and resolving whether or not to approve transactions with respect to the terms of office and employment of office holders; and (iv) resolving, under certain circumstances prescribed under the Companies Law, whether or not to exempt a transaction with a candidate for chief executive officer who meets non-affiliation criteria from shareholder approval.

Our Remuneration Committee will also oversee the administration of the Company s various compensation plans and arrangements, in particular, the incentive compensation, deferred compensation and equity based plans of the Company (and to the extent appropriate, of the subsidiaries of the Company) and assists the Board in fulfilling its responsibilities relating to the compensation of directors, the Chief Executive Officer and other office holders of the Company. In carrying out these duties, our Remuneration Committee will meet on an ad hoc basis. Under the Companies Law, our Remuneration Committee may need to seek the approval of the Board and the shareholders for certain compensation decisions as described above. Each designated member of our Remuneration Committee is an independent director in accordance with the Nasdaq Capital Market corporate governance requirements, as affirmatively determined by our Board. Mr. Nir, Ms. Yaron-Eldar and Mr. Marth are the current designated members of our Remuneration Committee. Upon approval of the additional external director within three months following the completion of this offering, such external director will become a member of the Remuneration Committee, at which time Mr. Marth will leave the Remuneration Committee.

Nominating Committee

Our Board does not currently have a nominating committee, as director nominees are presented by our Board to our shareholders based upon the nominations made by the Board itself, or in certain circumstances as prescribed by the Companies Law, by a shareholder or group of shareholders. Pursuant to the Listing Rules of the Nasdaq Capital Market, we currently intend to rely upon the exemption for foreign private issuers from the Nasdaq Capital Market corporate governance requirements related to independent director oversight of nominations to our Board and the adoption of a formal written charter or board resolution addressing the nominations process. See Nasdaq Capital Market Listing Rules and Home Country Practices.

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Internal Auditor

Under the 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:

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

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. We intend to appoint an internal auditor within three months from the closing of this offering.

Approval Required for Directors and Officers Compensation

Pursuant to the Companies Law, any arrangement between a public company and an office holder of the company as to such office holder s terms of office and employment, including exemption and release of the office holder from liability for breach of his or her duty of care to the company, an undertaking to indemnify the office holder, post factum indemnification or insurance, any grant, payment, remuneration, compensation, or other benefit provided in connection with termination of service and any benefit, other payment or undertaking to provide any such payment, generally requires the approval of the company s remuneration committee and the board of directors and, with respect to directors and the chief executive officer, also the approval of the company s shareholders.

The term office holder used in this section is as defined in the Companies Law and includes a general manager (or chief executive officer), executive vice president, vice president, any other person fulfilling or assuming any of the foregoing positions, without regard to such person s title, as well as a director or a manager directly subordinated to the general manager or chief executive officer.

In addition, pursuant to the Companies Law and within nine months following the consummation of this offering, we must adopt a policy for compensation of office holders, or the Compensation Policy, meeting the provisions of the Companies Law, and any arrangements with respect to the terms of office and employment of office holders thereafter must generally be consistent therewith.

The Compensation Policy must be based on certain considerations, must include certain provisions and needs to reference certain matters as set forth in the Companies Law. The Compensation Policy must be approved by the company s board of directors after considering the recommendations of the remuneration committee. In addition, the Compensation Policy needs to be approved by the company s shareholders by a simple majority, provided that (i) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the Compensation Policy, constitute two percent or less of the voting power of the company. Such majority determined in accordance with clause (i) or (ii) is hereinafter referred to as the Compensation Majority.

To the extent a Compensation Policy is not approved by shareholders, the board of directors of a company may override the resolution of the shareholders following a re-discussion of the matter by the board of directors and the remuneration committee and for specified reasons, and after determining that despite the rejection by the shareholders, the adoption of the Compensation Policy is for the benefit of the company.

A Compensation Policy that is for a period of more than three years must be approved in accordance with the above procedure every three years.

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Notwithstanding the above, the amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the approval of only the remuneration committee, if such committee determines that the amendment is not material in relation to its existing terms.

Compensation of Directors

Pursuant to the Companies Law, any arrangement between a company and a director as to his or her terms of office and employment, including with respect to any other roles the director may have at such company, must be consistent with the Compensation Policy and requires the approval of the remuneration committee, the board of directors and the shareholders by a simple majority. Under certain circumstances and conditions, the remuneration committee and the board of directors may approve an arrangement for a director that deviates from the Compensation Policy, provided that such arrangement is approved by the company's shareholders by the Compensation Majority.

Under the Companies Law and regulations promulgated pursuant thereto, the compensation payable to external directors and to directors who have been classified as independent directors under the Companies Law is subject to certain further limitations. See Management Board Practices External Directors & Financial Experts above.

Chief Executive Officer

Pursuant to the Companies Law, any arrangement between a company and its chief executive officer (who is not a director) as to his or her terms of office and employment must be consistent with the Compensation Policy and requires the approval of the remuneration committee, the board of directors and the company's shareholders by a Compensation Majority.

Under certain circumstances and conditions, the remuneration committee and the board of directors may approve an arrangement that deviates from the Compensation Policy provided it is approved by the shareholders by a Compensation Majority. In addition, under certain circumstances, a company may be exempt from receiving the shareholders approval with respect to the terms of office and employment of a candidate for chief executive officer who meets certain non-affiliation criteria.

In special circumstances, to the extent the terms of office and employment of the chief executive officer (who is not a director) are not approved by shareholders, the board of directors and the remuneration committee may override the resolution of the shareholders following a re-discussion of the matter and for specified reasons, and having considered the rejection by the shareholders of the matter.

Compensation of Other Office Holders

Pursuant to the Companies Law, any arrangement between a company and an office holder who is not either a director, the chief executive officer or a controlling shareholder (or relative of the controlling shareholder) as to his or her terms of office and employment must be consistent with the Compensation Policy and requires the approval of the remuneration committee and the board of directors.

Under certain circumstances and conditions, the remuneration committee and the board of directors may approve an arrangement that deviates from the Compensation Policy, provided that such arrangement is also then approved by the company s shareholders by a Compensation Majority. In addition, in special circumstances and to the extent not approved by shareholders, the board of directors and the remuneration committee may override the resolution of the

shareholders for specified reasons following a discussion of the matter and consideration of the rejection of the matter by the shareholders.

To the extent that any such compensation is for a controlling shareholder (or relative thereof) and is for a period extending beyond three years, shareholder approval is required once every three years by a Compensation Majority.

Following the consummation of this offering and until the adoption of a Compensation Policy by the Company, any arrangements with respect to the terms of office and employment of office holders will be approved as an arrangement which deviates from the Compensation Policy.

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For information regarding the aggregate compensation granted in 2013 to our executive officers and directors, see below Compensation of Our Executive Officers and Directors. For information regarding how we compensate our directors and certain office holders who are also related parties, see below Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties.

Nasdaq Capital Market Listing Rules and Home Country Practices

The Shares have been approved for listing on the Nasdaq Capital Market under the symbol GLMD. Upon the listing of the Shares on the Nasdaq Capital Market, in addition to the corporate governance requirements of the Sarbanes-Oxley Act and the related rules implemented by the SEC, we will need to comply with the Listing Rules of the Nasdaq Capital Market. Under those Listing Rules, we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Listing Rules of the Nasdaq Capital 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 Capital Market, when we list on the Nasdaq Capital Market we will follow the provisions of the Companies Law, rather than the Listing Rules of the Nasdaq Capital Market, with respect to the following requirements:

Distribution of certain reports to shareholders. As opposed to the Listing Rules of the Nasdaq Capital Market, which require listed issuers to make certain reports, such as annual reports, interim reports and quarterly 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 plan to 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. See Where You Can Find Additional Information for a description of our Exchange Act reporting obligations.

Nomination of directors. With the exception of our external directors and directors elected by our Board due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following three years from his or her election. See Management Board Practices. The nominations for directors, which are presented to our shareholders by our Board, are generally made by the Board itself, in accordance with the provisions of our Articles and the Companies Law. One or more shareholders of a company holding at least 1% of the voting power of the company may nominate a currently serving external director for an additional three year term. Nominations need not be made by a nominating committee of our Board consisting solely of independent directors or by independent directors constituting a majority of independent directors, as required under the Listing Rules of the Nasdaq Capital Market.

Compensation of officers. We follow the provisions of the Companies Law with respect to matters in connection with the composition and responsibilities of our Remuneration Committee, office holder compensation and any required approval by the shareholders of such compensation. Israeli law and our Articles do not require that the independent members of our Board, or a compensation committee composed solely of independent members of our Board, determine an executive officer s compensation, as is generally required under the Listing Rules of the Nasdaq Capital Market with respect to the Chief Executive Officer and all other executive officers of a company. Instead, our Remuneration Committee will be established and conduct itself in accordance with the provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law. Furthermore,

compensation of office holders is determined and approved by our Remuneration Committee, and in general, by our Board as well, and in certain circumstances by our shareholders, as detailed above. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect

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to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Listing Rules of the Nasdaq Capital Market. See Approval Required for Directors and Officers Compensation above.

According to the Companies Law, we will be obliged to establish a remuneration committee as detailed above. All members of our Remuneration Committee are independent directors under applicable Nasdaq Capital Market and SEC rules, as affirmatively determined by our Board.

Independent directors. Although Israeli law does not require that a majority of the directors serving on our Board be independent, as defined under Nasdaq Capital Market Listing Rule 5605(a)(2), but rather requires we have at least two external directors who meet the requirements of the Companies Law, as described above under Management Board Practices External Directors, upon the approval of our external directors, including an additional nominee not currently serving on our Board, within three months following this offering, we expect a majority of our Board to be independent based on the Nasdaq Capital Market rules. We are required, however, to ensure that all members of our Audit Committee are independent under the applicable Nasdaq Capital Market 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 Companies Law. However, while not required by Israeli law our independent directors will conduct regularly scheduled meetings at which only such independent directors are present, as required by the Nasdaq Capital Market Listing Rules. Our Board has affirmatively determined that each of Mr. Nir, Ms. Yaron-Eldar and Mr. Marth qualifies as independent under the Nasdaq Capital Market independence standards.

Shareholder approval. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with Nasdaq Capital Market Listing Rule 5635. In particular, under this Nasdaq Capital Market rule, shareholder approval is generally required for: (i) an acquisition of shares or 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 or 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 (or via sales by directors, officers or 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 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 remuneration 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 office and 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 Companies Law, a merger requires approval of the shareholders of each of the merging companies. See also Compensation of Officers above.

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Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The 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 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 a company. The duty of care includes a duty to use reasonable means to obtain:

information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

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 a company, and includes a duty to:

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;

refrain from any activity that is competitive with the company;

refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and

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 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 a 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 a 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 Companies Law, an extraordinary transaction is defined as any of the following:

a transaction other than in the ordinary course of business;

a transaction that is not on market terms; or

a transaction that may have a material impact on a company s profitability, assets or liabilities.

If an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the articles of association of a company provide for a different method of approval. Our Articles do

not provide for any such 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 the duty of loyalty. However, a company may not

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approve a transaction or action that is adverse to such company s interest or that is not performed by the office holder in good faith. Approval first by a 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 remuneration committee, board of directors and, in certain circumstances, the shareholders, in that order, as described above under Nasdaq Capital Market Listing Rules and Home Country Practices Compensation of Officers and Nasdaq Capital Market Listing Rule 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 a 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 under his or her control, require the approval of the audit committee, the board of directors and the shareholders of a company, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

a disinterested majority; or

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 2% of the voting rights of a 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, with respect to extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, 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 a company, require the approval of the remuneration committee, board of directors and the shareholders (by the Compensation Majority described above), in that order, as described above under Nasdaq Capital Market Listing Rules and Home Country Practices Compensation of Officers.

Shareholder Duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward a 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:

an amendment to the company s articles of association;
an increase of the company s authorized share capital;

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a merger; or

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 a 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 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 and Indemnification of Directors and Officers

Under the 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 the duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our Articles 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 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:

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;

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

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 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:

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 such act would not prejudice the company;

a breach of the duty of care to the company or to a third-party; and

a financial liability imposed on the office holder in favor of a third-party.

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

a breach of the duty of loyalty, 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;
a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
an act or omission committed with intent to derive unlawful personal benefit; or
a fine, monetary sanction, penalty or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders require the approval of the remuneration committee, board of directors and, in certain circumstances, the shareholders, as described above under Nasdaq Capital Market Listing Rules and Home Country Practices Compensation of Officers.

Our Articles permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted by the Companies Law. Each of our office holders have entered into an indemnification agreement with us.

In addition, we will enter into agreements with each of our office holders, to become effective immediately prior to this offering, which will replace and supersede each indemnification agreement previously entered into by such office holders with the Company, exculpating them, to the fullest extent permitted by Israeli law, from liability to us for damages caused to us as a result of a breach of the duty of care and undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from certain acts performed by such office holders in their capacity as an office holder of the Company, our subsidiaries or our affiliates. In accordance with each such new indemnification agreement, we will agree to indemnify our office holders for certain liabilities resulting from this offering. The indemnification is limited both in terms of amount and coverage.

In the opinion of the SEC, indemnification of directors and office holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

Insurance

In addition to the indemnification agreements described above, we have obtained directors and officers liability insurance with maximum coverage of $2.0 million in the aggregate for the benefit of our office holders and directors, and we intend to purchase an initial public offering policy with maximum coverage of $20 million in the aggregate and an additional $5 million Side A difference in conditions (DIC) policy for our initial public offering and pay all premiums thereunder to the fullest extent permitted by the Companies Law. Such directors and officers liability insurance contains certain standard exclusions.

We also maintain insurance for our offices in Tel Aviv, Israel. Our insurance program covers approximately NIS 111,000 (or $30,748 based on an exchange rate of NIS 3.61 = $1.00, which reflects the average exchange rate for the year ended December 31, 2013) of equipment and lease improvements against risk of loss, excluding damage from inventory theft. In addition, we maintain the following insurance: employer liability with coverage of approximately NIS 18.4 million (or $5.1 million based on an exchange rate of NIS 3.61 = $1.00 which reflects the average exchange rate for the year ended December 31, 2013); third-party liability with coverage of approximately NIS 6.0 million (or $1.7 million based on an exchange rate of NIS 3.61 = $1.00 which reflects the average exchange rate for the year ended December 31, 2013); fire peril coverage of approximately NIS 180,000 (or $49,861 based on an exchange rate of NIS 3.61 = $1.00 which reflects the average exchange rate for the year ended December 31, 2013); natural disaster

coverage of approximately NIS 180,000 (or $49,861 based on an exchange rate of NIS 3.61 = $1.00 which reflects an average conversion rate for 2013); and all risk coverage of approximately NIS 45,000 (or $12,465 based on an exchange rate of NIS 3.61 = $1.00 which reflects the average exchange rate for the year ended December 31, 2013) for electronic equipment and machinery insurance for laboratory refrigerators.

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We also intend to purchase worldwide product and clinical trial liability insurance to cover each of our clinical trials studies with respect to the aramchol drugs used in clinical trials in accordance with applicable local regulations in the territories in which the studies will take place. We also procure additional insurance for each specific clinical trial which covers a certain number of trial participants and which varies based on the particular clinical trial. Certain of such policies are based on the Declaration of Helsinki, which is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association, and certain protocols of the Israeli Ministry of Health.

We believe that our insurance policies are adequate and customary for a business of our kind. However, because of the nature of our business, we cannot assure you that we will be able to maintain insurance on a commercially reasonable basis or at all, or that any future claims will not exceed our insurance coverage.

Code of Business Conduct and Ethics

We intend to adopt 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 and as required by the Nasdaq Capital Market Listing Rules, which refers to Section 406(c) of the Sarbanes-Oxley Act. Section 406(c) of the Sarbanes-Oxley Act provides that a code of ethics means such standards as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the issuer; and (iii) compliance with applicable governmental rules and regulation.

Upon the adoption of the Code of Business Conduct and Ethics, the full text of the Code of Business Conduct and Ethics will be posted on our website at *www.galmedpharma.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 Business Conduct and 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, including Item 16B of Form 20-F.

Compensation of Our 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, 2013 was approximately $7.5 million. This amount includes approximately $223,000 set aside or accrued to provide pension, severance, retirement, vacation 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 December 31, 2013, options to purchase 1,463 shares of GHI (or 1,066,527 of our ordinary shares, calculated on a post-Reorganization basis) granted to our officers and directors as a group were outstanding, of which options to purchase 1,233 shares of GHI (or 898,857 of our ordinary shares, calculated on a post-Reorganization basis) were vested, with a weighted average exercise price of $2,601.41 per share of GHI (or $3.57 per our ordinary share, calculated on a post-Reorganization basis). All such options expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering. See Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties The

Warrant.

As of February 27, 2014, options to purchase 833,811 of our ordinary shares granted to our officers and directors as a group were outstanding of which options to purchase 746,331 of our ordinary shares were vested, with a weighted average exercise price of $1.02 per ordinary share. This number includes fully-vested options to purchase 8,583 ordinary shares that we granted to Mr. Nir in consideration for his services as our director until the consummation of this offering. However, this number excludes 17,166 ordinary shares issuable upon the exercise of options which will be granted under our 2013 Plan to Mr. Marth upon the consummation of this offering and 177,488 ordinary shares issuable upon the exercise of the Warrant granted to our Chairman, Mr. Chaim Hurvitz, which will be exercised automatically upon the completion of this

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offering, by way of cashless exercise, based upon the initial public offering price of $13.50 per Share. All such options expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering. See Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties The Warrant.

Other than with our Chief Executive Officer, as detailed in Employment Agreements and Arrangements with Directors and Related Parties Services and Employment Agreements with Our Chief Executive Officer, we do not have written agreements with any director providing for benefits upon the termination of his or her services with our Company.

We have entered into a written employment agreement with our Chief Executive Officer. This agreement contains 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 Related to Our Business, Industry and Regulatory Requirements for a further description of the enforceability of non-competition clauses. See Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties below 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 and shareholders. See Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties for additional information.

Services of our Directors

In connection with their services as directors of the Company following the completion of this offering, each of our directors will be entitled to an annual payment of $30,000, plus VAT, if applicable, payable quarterly at the end of each quarter.

In addition, upon the completion of this offering, Mr. Marth will be entitled to options to purchase 17,166 of our ordinary shares, which will vest on a quarterly basis over a period of three years commencing on the date of the consummation of the offering, such that 8.33% of the options shall vest at the end of each quarter. The exercise price of such options is $3.57 per share and each will expire in September 2023.

Services of our External Directors

Subject to shareholder approval within three months following the consummation of this offering, Ms. Tali Yaron-Eldar and another individual to be identified and selected by our Board following the offering, will serve as our external directors beginning upon receipt of such shareholder approval. In connection with their services as external directors of the Company, and subject to shareholder approval which we expect to receive on the same date, each of the external directors will be entitled to an annual amount of $30,000, payable quarterly at the end of each quarter. The compensation of external directors is subject to the provisions of the Compensation Regulations which provide that such compensation will not be less than the Minimum Amount (as such term is defined in the Compensation Regulations) See Board Practices External Directors & Financial Experts above for additional information with respect of external directors.

2013 Incentive Share Option Plan

We maintain one equity-based incentive plan, our 2013 Incentive Share Option Plan, or our 2013 Plan. As of February 27, 2014, a total of 2,340,492 shares were reserved for issuance under our 2013 Plan, of which options to purchase 1,539,472 ordinary shares were issued and outstanding thereunder. This number excludes 17,166 ordinary shares issuable upon the exercise of options which will be granted upon the consummation of this offering under our 2013 Plan to Mr. Marth. Of such outstanding options, options to purchase 1,315,755 ordinary shares were vested as of February 27, 2014, with a weighted average exercise price of $1.26 per share, and will expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering.

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The above does not include a fully-vested option to purchase 38,637 shares granted to a service provider, which was not granted under the 2013 Plan, and which has no expiration date.

Our 2013 Plan, which was adopted by our Board on September 2, 2013, provides for the grant of options to purchase our ordinary shares to our and our affiliates respective directors, employees, office holders, service providers and consultants.

The 2013 Plan is administered by our Board, which, on its own or upon the recommendation of a remuneration committee or any other similar committee of the Board, shall determine, subject to applicable law, the identity of grantees of awards and various terms of the grant. The 2013 Plan provides for granting options to purchase our ordinary shares to directors, officers and employees, who are not holders of 10% or more of our total share capital and are not otherwise controlling shareholders, in Israel pursuant to Section 102 of the Israeli Income Tax Ordinance, or the Ordinance, under the capital gains track, and for grants to non-employee Israeli service providers, consultants and shareholders who hold 10% or more of our total share capital or are otherwise controlling shareholders pursuant to Section 3(i) of the Ordinance, as further detailed below. For residents, or deemed residents, of the United States, such grants are pursuant to Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, as an Incentive Stock Option, or ISO, and any other participants which do not qualify for ISOs, as a Non-statutory Stock Options, or NSO, pursuant to the Code.

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 non-employee Israeli service providers, consultants and controlling shareholders, which includes any shareholder holding 10% or more of the Company s ordinary shares on a fully diluted basis, may only be granted options under Section 3(i) of the Ordinance, which does not provide for similar tax benefits. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, the most favorable tax treatment for grantees, permits the issuance to a trustee under the capital gains track. However, under this track we are not allowed to deduct any 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 2013 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. If such options or shares are sold by the trustee or are transferred to the grantee before the end of the two year period, then the grantee would be taxed at top marginal rates upon selling the shares.

Section 422 of the Code allows employees, directors and officers, who are non-controlling shareholders (e.g., less than 10% shareholders) and are considered residents of the United States or those who are deemed to be residents of the United States for purposes of the payment of tax, or are otherwise subject to taxation in the United States with respect to the grant of awards, to receive favorable tax treatment for compensation in the form of shares or ISOs. 10% shareholders or persons which are not service providers will receive NSOs, which do not entitle them to receive similar tax benefits. Section 422(b) of the Code provides for the ISO track such that the individual does not have to pay ordinary income tax (nor employment taxes) on the difference between the exercise price and the fair market value of the shares issued (however, the holder may have to pay U.S. alternative minimum tax instead). However, if the shares are held for one year from the date of exercise and two years from the date of grant, then the profit (if any) made on sale of the shares is taxed as long-term capital gain. Section 422 of the Code requires that any grant of awards shall not be made at a price which is less than 100% of the fair market value of such awards on the date of the grant, all pursuant to the terms of Section 409A of the Code. However, under this ISO track, we are not allowed to

deduct any expense with respect to the issuance of the options or shares. In order to comply with the terms of the ISO track, the option granted thereunder must meet the requirements of Section 422 of the Code when granted and at all times until the exercise thereof.

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Options granted under the 2013 Plan will in accordance with the vesting dates as determined by the Board or a remuneration committee or any other similar committee of the Board with respect to each grant. Options that are not exercised within ten years from the grant date expire, unless otherwise determined by the Board the Remuneration 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 twelve 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 unexercised options will expire and terminate 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 or within a longer period under specified circumstances. Any expired or unvested options return to the option pool reserved under the 2013 Plan for reissuance.

In the event of a merger or consolidation of our company subsequent to which we would no longer exist as a legal entity, or a sale of all, or substantially all, of our ordinary shares or assets or other transaction having a similar effect on us, or a Transaction, any unexercised options then outstanding will be cancelled. Notwithstanding the foregoing, the Board, or the relevant committee of the Board, may determine that the options will not be cancelled but will be assumed or substituted for an appropriate number of the same type of shares or other securities of the successor company as were distributed to the Company or the shareholders in connection with the Transaction. In addition, the Board, or the relevant committee of the Board, may determine to include in certain option agreements either a clause that provides for acceleration of vesting of all or part of the unvested options in the event of a Transaction or the occurrence of another event or a clause which provides that if the optionee s employment with the successor company is terminated by the successor company without cause within a certain period, not to exceed two years from the closing of such Transaction, all or part of the unvested options shall be accelerated.

Certain Relationships and Related Party Transactions

The following is a summary description of the material terms of those transactions with related parties to which we, or our subsidiaries, are party and which were in effect within the past three fiscal years.

Convertible Bridge Loan Agreements (2009 2011)

Between 2009 and December 2011, our predecessor, GHI, entered into a series of bridge loans with its shareholders and certain external lenders, or the Bridge Loans. Pursuant to the Bridge Loans, GHI received an aggregate principal amount of $1,824,300, bearing no interest, of which G. Yarom Medical Research Ltd., which is controlled by our Chief Executive Officer, loaned $100,000. The Bridge Loans were convertible into ordinary shares of GHI or any of its successors, either automatically upon the closing of a round of equity financing in GHI of not less than $1,000,000, or at the option of each lender into such number of ordinary shares of GHI representing a company pre-money valuation of $25,000,000. In 2011, in connection with the Convertible Loan Agreement, as referenced below, the lenders and GHI agreed that the aggregate principal amount of the Bridge Loans would convert into ordinary shares of GHI upon the conversion of the Convertible Loan, at the same conversion price per share. On December 22, 2013, all outstanding amounts under the Bridge Loans were converted into ordinary shares of GHI.

Convertible Loan Agreement (December 2011)

Pursuant to a convertible loan agreement, or the Convertible Loan Agreement, GHI received an aggregate principal amount of approximately $3,724,512, bearing no interest, of which Shirat HaChaim Ltd., which is controlled by our Chairman, loaned $2.5 million. The loans extended under the Convertible Loan Agreement were convertible into ordinary shares of GHI, or any of its successors, at a conversion price of $3.57 per share on a post-Reorganization

basis, on January 1, 2013. The loans extended under the Convertible Loan Agreement were not repayable in cash.

On December 22, 2013, all outstanding amounts under the Bridge Loans and the Convertible Loan Agreement were converted into 2,133 shares of GHI, of which 38 shares were issued to G. Yarom Medical Research Ltd., and 961 shares were issued to Shirat HaChaim Ltd. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to all such shareholders 1,554,957 ordinary shares, which

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shares represent the same percentage of our share capital as such 2,133 shares represented of the share capital of GHI, and of which 700,569 shares were issued to Shirat Hachaim Ltd. and 27,702 shares were issued to G. Yarom Medical Research Ltd.

Convertible Security Notes (August and September 2013)

In August and September 2013, GHI issued to its shareholders convertible security notes, or the Convertible Security Notes, convertible into ordinary shares of GHI, or any of its successors, in an aggregate amount of $1,839,700, or the Purchase Price. $200,000 of such Convertible Security Notes were issued to G. Yarom Medical Research Ltd., which is controlled by our Chief Executive Officer, and $150,000 of such Convertible Security Notes were issued to Shirat HaChaim Ltd., which is controlled by our Chairman. The Convertible Security Notes expire upon the earlier of (i) the conversion of the Purchase Price upon the closing of an equity financing in an aggregate amount of no less the $2,000,000, or a Qualified Equity Financing, and (ii) the exchange of each Convertible Security Note into a debt financing instrument issued under a qualified debt financing in an aggregate amount of no less than $2,000,000. Prior to Qualified Equity Financing, the holders of the Convertible Security Notes may convert their Convertible Security Notes into shares of GHI, or any of its successors, at a conversion price of $7.45 per share on a post-Reorganization basis, representing a company valuation of $60,000,000, on a fully diluted basis or demand the repayment of the Purchase Price in full without interest. However, upon the consummation of, or following, a Qualified Equity Financing, the Convertible Security Notes may be converted by their respective holders into the same shares issued by GHI, or any of its successors, in such financing, at a price per share equal to 80% of the price per share payable by the investors in the Qualified Equity Financing. On December 10, 2013, pursuant to an amendment letter entered into between the Company and the lenders holding more than 75% of the Purchase Price, all Convertible Security Notes were converted by their respective holders into 707 shares of GHI at a conversion price of $2,601.41 per share, of which 77 shares were issued to G. Yarom Medical Research Ltd. and 58 shares were issued to Shirat HaChaim Ltd. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to such shareholders 515,403 of our ordinary shares, which shares represent the same percentage of our share capital as such 707 shares represented of the share capital of GHI, and of which 56,133 ordinary shares were issued to G. Yarom Medical Research Ltd. and 42,282 shares were issued to Shirat HaChaim Ltd.

Share Purchase Agreement (December 2013)

On December 31, 2013 our predecessor, GHI, entered into a share purchase agreement with Shirat HaChaim Ltd., which is controlled by our Chairman, pursuant to which GHI issued to Shirat HaChaim Ltd., 46 ordinary shares of GHI, for a total investment amount of $120,000, at a price per share of $2,601.41. In connection with the Reorganization and in accordance with the Tax Pre-Ruling, we issued to such shareholder 33,534 of our ordinary shares for no additional consideration, which shares represent the same percentage of our share capital as such 46 ordinary shares represent of the share capital of GHI.

Share Purchase Agreement (February 2014)

On February 3, 2014 we entered into a share purchase agreement with certain of our shareholders and new investors, or the Share Purchase Agreement, pursuant to which we issued to such existing shareholders and new investors 560,224 ordinary shares at a price per share of $3.57 for a total investment amount of $2.0 million.

Registration and Information Rights Agreement

On December 30, 2013, in connection with the Reorganization, we entered into a registration and information rights agreement, on substantially the same terms as, and to replace, a prior investors rights agreement entered into on December 21, 2011 between GHI and certain of its shareholders, or the Registration Rights Agreement. As of the date hereof, each of the holders of at least 1% of our ordinary shares is entitled to be a party to the Registration Rights Agreement, either as an original signatory or as an assignee or transferee of our ordinary shares, including Shirat HaChaim Ltd., which is an entity controlled by our Chairman, and G. Yarom Medical Research Ltd., which is controlled by our Chief Executive Officer, David and Debora Goldfarb and Medgal Holdings S.A. We will refer to these shareholders, excluding Shirat HaChaim Ltd., as the Other Shareholders. The Registration Rights Agreement contains provisions regarding registration rights as set forth below.

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Demand Registration Rights. At any time beginning six months following the effective date of this offering, upon a request of either Shirat HaChaim Ltd. or at least 40% of the registrable securities held by the Other Shareholders, we are required to use commercially reasonable efforts to register such requesting shareholders ordinary shares under the Securities Act, but only if the aggregate offering price of the shares to be registered is at least $5,000,000. We are not required to effect more than two demand registrations; one registration upon the request of Shirat HaCahim Ltd. and the other upon a request of at least 40% of the registrable securities held by the Other Shareholders.

Piggyback Registration Rights. All of our shareholders that are a party to the Registration Rights Agreement have the right to request that we include their registrable securities in any registration statement that we file in connection with public offerings of our shares and resale registrations, except for certain excluded registrations, such as registrations of shares issued under employee benefit plans, a registration relating to a corporate reorganization or a registration on a form that does not include substantially the same information as would be required to be included in a registration statement covering the sales of registrable securities. If such public offering is underwritten, the right of any shareholder to include shares in the registration related thereto is conditioned upon the shareholder accepting the terms of the underwriting agreement between us and the underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not materially and adversely jeopardize the success of such offering.

Form F-3 Registration. At any time after we become eligible under applicable securities laws to file a registration statement on Form F-3, upon a written request of Shirat HaChaim Ltd. or the holders of at least 40% of the registrable securities held by the Other Shareholders, we will be required to register such shareholders ordinary shares under the Securities Act, but only if the aggregate offering price of the shares to be registered is at least $3,000,000. We are not required to effect more than two registrations on Form S-3 in any 12 month period.

Registration Preference. In the event that we register shares of our shareholders in an initial public offering or in any subsequent registration, Shirat HaChaim Ltd. has a preference over all other shareholders to register and sell its shares. In which case, the shares of all other shareholders to be registered will be reduced accordingly. However, in any registration initiated by us, the shares held by us or to be issued by us have such a preference over all other shareholders, including Shirat HaChaim Ltd.

Expenses. We have agreed to pay all expenses incurred in carrying out the above registrations, including the reasonable fees of one counsel chosen by the selling shareholders that are a party to the Registration Rights Agreement, but excluding discounts or commissions payable to any underwriter; provided however, with respect to any registration initiated pursuant to a shareholder s demand rights, as set forth above, we will not be required to pay for any expenses if the registration is later withdrawn at the request of a majority holders of the shares to be registered, unless such holders agree to forfeit their right to each of their respective demand registrations.

The Registration Rights Agreement is silent with respect to term and termination provisions. However, it provides that we are not required to register shares of holders of less than 1% of our ordinary shares on a fully diluted basis if such shares may be sold pursuant to Rule 144 under the Securities Act.

Shareholders Rights Agreement

On December 30, 2013, in connection with the Reorganization, we entered into a shareholders rights agreement, on substantially the same terms as, and to replace, a prior shareholders' rights agreement entered into on December 21, 2011 between GHI and certain of its shareholders, or the Shareholders Rights Agreement. Pursuant to the Shareholders Rights Agreement, the shareholders party thereto agreed to vote their ordinary shares for the election of our directors as follows: two directors designated by G. Yarom Medical Research Ltd., one director designated by

Shirat Hachaim Ltd., one director designated by the holders of the majority of the ordinary shares held by David and Debora Goldfarb and Medgal Holdings S.A. and additional directors (including any additional directors whose office may become vacated from time to time) designated by the majority vote of the directors then in office or by the shareholders of the Company at a general meeting. Furthermore, according to the Shareholders Rights Agreement, the ordinary shares held by David and Debora Goldfarb and Medgal Holdings S.A. are to be aggregated for the purpose of determining the eligibility

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of the parties to any rights granted to major shareholders under our articles of association in effect prior to the offering. Each such shareholder is exercising the voting and/or disposition powers on its respective shares separately.

The Shareholders Rights Agreement will be terminated immediately upon the consummation of the offering.

Employment Agreements and Arrangements with Directors and Related Parties

We entered into written employment agreements with each of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition and assignment of inventions provisions may be limited under applicable law. See Risk Factors Risks Related to Our Business, Industry and Regulatory Requirements.

Services and Employment Agreements with Our Chief Executive Officer

We entered into an employment agreement, dated December 23, 2013, with our Chief Executive Officer, Mr. Allen Baharaff, who is also a controlling shareholder, which was approved and ratified by our shareholders on December 30, 2013. Under the terms of his employment agreement, Mr. Baharaff is entitled to a gross monthly salary of $20,000. In addition, Mr. Baharaff will be eligible to receive (i) an annual bonus in an amount of two to six times his monthly base salary, to be determined based on the achievement of certain milestones set by our Board, (ii) a special bonus of $200,000 in recognition of his efforts and contribution with respect to the consummation of this offering and (iii) upon the termination of his employment, special remuneration of nine times his gross monthly salary as consideration for certain noncompetition provisions contained in his employment agreement. Mr. Baharaff will also receive other benefits required under Israeli law or that are customary for senior executives in Israel such as reimbursement for cellular telephone expenses, automobile or automobile maintenance expenses, and company contributions equivalent to 5%, 8.33%, 2.5% and 7.5% of his gross monthly base salary towards certain pension, or a manager s insurance policy, severance, disability and tax-advantaged savings funds, or a study fund, respectively. Mr. Baharaff will also contribute 5% and 2.5% of his gross monthly salary towards the manager's insurance policy and study fund, respectively. Mr. Baharaff s employment agreement is terminable by either party upon 90 days prior written notice, and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

We also granted Mr. Baharaff, pursuant to his employment agreement, options to purchase 174,960 of our ordinary shares, 50% of which will vest as of January 1, 2014 and the remaining 50% will vest over a period of two years on a quarterly basis. All of such options are subject to the terms and conditions of our 2013 Plan and his option agreement. The exercise price of such options is $0.53 per share and each will expire in September 2023.

Prior to his employment agreement, Mr. Baharaff provided services to us thorough a services agreement between GMR and Aram Baharaff Consultants Ltd., or the Service Provider, a private Israeli company wholly-owned by Mr. Baharaff, pursuant to a services agreement, dated January 1, 2007, or the Services Agreement. According to the Services Agreement, Mr. Baharaff served us, including as the chief financial officer of GMR, for 80 hours per month in consideration of $10,000 per month. On December 18, 2011, GMR received an executed letter of Confirmation & Release from the Service Provider, irrevocably waiving its entitlement to the amount of $430,000, which represented accumulated unpaid service fees between the years 2007 and 2011. Due to an increase in the scope of his services, we

subsequently increased the Service Provider s monthly fees to $20,000, effective as of January 1, 2012. On December 30, 2013, we granted Mr. Baharaff fully-vested options to purchase 150,903 of our ordinary shares. In addition, Mr. Baharaff waived $350,000 payable to him pursuant to the Services Agreement. The Services Agreement was terminated on December 31, 2013.

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As of February 27, 2014, Mr. Baharaff holds options to purchase a total of 742,122 of our ordinary shares. All such options were granted under our 2013 Plan. The exercise price of 567,162 of such options is NIS 0.01 per share and the exercise price of 174,960 of such options is $0.53 per share. All such options will expire in September 2023.

Services of Dr. Maya Halperin

We entered into an employment agreement with Dr. Maya Halperin, our Chief Medical Officer and a member of our Board, dated December 23, 2013, on a part-time basis. Under her employment agreement, which will become effective as of February 2014, Dr. Halperin is entitled to a gross monthly salary of NIS 20,000 (which is equivalent to US$ 5,540 based on an exchange rate of NIS 3.61 per $1.00, which reflects the average exchange rate for the year ended December 31, 2013) per month. In addition, Dr. Halperin will be eligible to receive other benefits required under Israeli law or that are customary for senior executives in Israel, including entitlement for travel expenses and company contributions equivalent to 5%, 8.33%, 2.5% and 7.5% of her gross monthly base salary towards certain pension, or a manager s insurance policy, severance, disability and tax-advantaged savings funds, or a study fund, respectively. Dr. Halperin will also contribute 5% and 2.5% of her gross monthly salary towards the manager's insurance policy and study fund, respectively. The employment agreement is terminable by either party upon 60 days prior written notice and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

We granted Dr. Halperin 64,152 fully-vested options to purchase a like amount of our ordinary shares, which are subject to the terms and conditions of our 2013 Plan and her option agreement. The exercise price of such options is $3.57 per share and each will expire in September 2023.

Services Agreement with Diamond Biopharm Limited

Dr. Maureen Graham, our Vice President Regulatory, and Dr. Antony Appleyard, our Vice President Drug Development, provide us with services pursuant to a services agreement, dated February 2, 2012, as amended on September 6, 2012 and on December 27, 2013, or the Diamond Services Agreement, with Diamond Biopharm Limited, a company formed in the United Kingdom, controlled by Dr. Graham and which employs Dr. Graham and Dr. Appleyard, or Diamond. According to the Diamond Services Agreement, Diamond provides us with consulting services and assistance with respect to our product research and development, as well as with European regulatory and compliance matters. The Diamond Services Agreement is generally terminable by either party upon 30 days prior written notice and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. The consideration payable to Diamond under the agreement is for time spent providing the services, calculated on a seven-hour per day basis, at the following rates: 1,000 British Pounds Sterling per day for the services of a director of Diamond, including Dr. Graham and Dr. Appleyard, £750 per day for the services of a manager of Diamond and £550 per day for the services of an operations staff member of Diamond.

We granted each of Dr. Graham and Dr. Appleyard fully-vested options to purchase 9,477 of our ordinary shares, which are subject to the terms and conditions of our 2013 Plan and their respective option agreements. The exercise price of such options is $3.57 per share and each will expire in September 2023.

The Warrant

Pursuant to the Convertible Loan Agreement, GHI granted our Chairman, Mr. Chaim Hurvitz, a warrant to purchase 331 of the ordinary shares of GHI, at an exercise price per share of $2,601.41, or the Old Warrant. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we granted Mr. Hurvitz a new warrant to purchase our

ordinary shares, or the Warrant, which was issued under our 2013 Plan, at an exercise price per share of $3.57, to replace the Old Warrant. The Warrant will automatically become fully vested upon the closing of this offering and will be exercised simultaneously with such vesting by way of a cashless exercise into 177,488 ordinary shares, based upon the initial public offering price of $13.50 per Share. See Capitalization above. The ordinary shares underlying the Warrant represent the same percentage of our share capital as the shares underlying the Old Warrant represented of the share capital of GHI.

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Confirmation and Release Letter from the Beneficiaries of the late Professor Tuvia Gilat

The late Professor Tuvia Gilat, our co-founder, was employed by GHI, our predecessor, as its chief executive officer between January 2001 and December 2010, at which time he left due to severe illness. Professor Tuvia Gilat passed away in 2011. On December 18, 2011, we reached a final and conclusive settlement, or the Settlement, with all of Prof. Gilat's beneficiaries, which includes our current Chief Executive Officer, pursuant to his last will and testament, or the Beneficiaries. According to the Settlement, the Beneficiaries will receive, collectively, a special payment equal to the gross amount of $263,200 in consideration for all of Mr. Gilat's rights and entitlements in connection with his employment with us and the termination thereof, including all social benefit deductions under Israeli law. The amount of the Settlement will be paid from our annual net profits, if any, and will bear an annual compounding interest rate of the 12 month U.S. dollar LIBOR plus 1%, effective retroactively from October 1, 2011. Pursuant to the Settlement, we have agreed not to distribute any dividends to our shareholders until the amount of the Settlement, including interest thereon, is paid in full.

As of February 27, 2014, the total Settlement amount outstanding, including interest, payable to the Beneficiaries is $275,810.

Financing Agreement with GRD

Following the completion of the offering, we may enter into a financing agreement with GRD pursuant to which we may provide financing to GRD in amounts to be agreed between the parties from time to time. We expect that all amounts transferred to GRD under such agreement would constitute investment in GRD and would not bear any interest.

Research and Development Agreement between GRD and GIL

Following the completion of the offering, GRD and GIL may enter into a research and development agreement pursuant to which GIL may provide GRD with certain research and development services, on a cost plus basis or other transfer pricing methodology.

Management and Director Interlocks

Our Chief Executive Officer and member of our Board, Mr. Allen Baharaff, also serves as a member of the board of directors of GMR and GIL, and as our natural person representative of GRD s board of directors. Mr. Baharaff does not receive additional compensation for such directorships.

Each of our Chairman, Mr. Hurvitz, our Chief Medical Officer and member of our Board, Dr. Halperin, and Mr. Nir, who serves as a member of our Board, also serve as members of the board of directors of GMR, and do not receive additional compensation for such directorship.

Indemnification Agreements

Our Articles permit us to exculpate, indemnify and insure each of our directors and officers to the fullest extent permitted by the Companies Law. Each of our office holders have entered into an indemnification agreement with us.

In addition, we will enter into agreements with each of our office holders, to become effective immediately prior to this offering, which will replace and supersede each indemnification agreement previously entered into by such office holders with the Company, exculpating them, to the fullest extent permitted by law, from liability for monetary or other damages due to, or arising or resulting from, a breach of the duty of care to the Company and undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from certain acts performed by such office holders in their capacity as an office holder of the Company, our subsidiaries or our affiliates. In accordance with each such new indemnification agreement, we will agree to indemnify our office holders for certain liabilities resulting from this offering. The indemnification is limited both in terms of amount and coverage. We have also obtained directors and officers insurance for each of our officers and directors. For further information, see Management Exculpation, Insurance and Indemnification of Directors and Officers above.

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PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our ordinary shares as of February 27, 2014 held by: (i) the only persons or entities known by the Company to beneficially own 5% or more of the outstanding ordinary shares; and (ii) our directors and executive officers, individually and 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, warrants or other conversion rights currently exercisable or that are exercisable within 60 days after February 27, 2014 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options, warrants or other conversion rights 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 7,659,955 ordinary shares outstanding on February 27, 2014. The number of ordinary shares deemed outstanding after this offering includes the Shares being offered for sale in this offering, and assumes the conversion of all outstanding notes under the Bridge Loans and the Convertible Loan Agreement, as well as the conversion of the Convertible Security Notes, but assumes no exercise of the underwriter s over-allotment option.

As of February 27, 2014, there were 47 record holders of our ordinary shares, most of whom reside in Israel. As of February 27, 2014, there were nine U.S. record holders of our ordinary shares (with a trustee holding ordinary shares on behalf of five shareholders and three shareholders holding ordinary shares jointly as beneficiaries of a deceased former shareholder) holding an aggregate of 4.78% of our ordinary shares on a fully diluted basis.

None of our shareholders has different voting rights from other shareholders. To the best of our knowledge, prior to the offering, we are controlled by G. Yarom Medical Research Ltd., a company incorporated under the laws of the State of Israel, which is controlled by our Chief Executive Officer, Allen Baharaff. However, following the offering, to the best of our knowledge, we will not be owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any natural person or legal persons, severally or jointly. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

	Prior to the offering		After the offering	
	Number of ordinary shares beneficially owned	Percentage of ordinary shares beneficially owned	Number of ordinary shares beneficially owned	Percentage of ordinary shares beneficially owned
Holders of more than 5% of our voting securities:				
Allen Baharaff[1][3]	4,082,400	49.03 %	4,082,400	36.00 %
Chaim Hurvitz[2][3]	953,873	12.17 %	953,873	8.94 %
David and Debora Goldfarb[4]	518,319	6.77 %	518,319	4.86 %
Medgal Holdings S.A.[5]	343,438	4.48 %	343,438	3.22 %
Directors and executive officers who are not 5% holders:				
Dr. Maya Halperin	64,152	*	64,152	*
Shmuel Nir[3][6]	50,021	*	50,021	*
Dr. Maureen Graham	9,477	*	9,477	*
William Marth[7]	0	*	0	*

Dr. Antony Appleyard	9,477	*	9,477	*
Ray Morris	0	*	0	*
Tali Yaron-Eldar[7]	0	*	0	*
All directors and executive officers as a group (9 persons):	5,169,400	60.15 %	5,169,400	45.22 %

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* Less than 1%

(1) Ordinary shares beneficially owned consist of (i) 3,416,823 ordinary shares, of which 56,133 ordinary shares, calculated on a post-Reorganization basis, were issued on December 10, 2013 upon conversion of the Convertible Security Notes and 27,702 shares, calculated on a post-Reorganization basis, were issued on December 22, 2013 upon the conversion of the Bridge Loans and the Convertible Loan Agreement, and (ii) options to purchase 665,577 shares that are currently exercisable or will be exercisable within 60 days from the date hereof, of which 567,162 have an exercise price per share of NIS 0.01 and will expire in September 2023 and 98,415 have an exercise price per share of $0.53 and will expire in September 2023. All such options were granted on December 30, 2013. Allen Baharaff s holdings in the company are through G. Yarom Medical Research Ltd., a company incorporated under the laws of the State of Israel. Mr. Baharaff is the controlling shareholder in G. Yarom Medical Research Ltd. and the chairman of its board of directors.

(2) Ordinary shares beneficially owned consist of (i) 776,385 ordinary shares held through Shirat HaChaim Ltd., a company incorporated under the laws of the State of Israel, of which Chaim Hurvitz is the controlling shareholder and the chairman of its board of directors, of which 42,282 ordinary shares, calculated on a post-Reorganization basis, were issued on December 10, 2013 upon conversion of the Convertible Security Notes and 700,569 shares, calculated on a post-Reorganization basis, were issued on December 22, 2013 upon the conversion of the Bridge Loans and the Convertible Loan Agreement, and 33,534 ordinary shares issued pursuant to the share purchase agreement, dated December 31, 2013, and (ii) 177,488 ordinary shares issuable upon the exercise of the Warrant, which will be exercised automatically upon the consummation of this offering by way of a cashless exercise, based upon the initial public offering price of $13.50 per Share. See Certain Relationships and Related Party Transactions Employment Agreements and Arrangements with Directors and Related Parties The Warrant.

(3) All options included are either currently exercisable or will be exercisable within 60 days from the date hereof.

(4) Ordinary shares beneficially owned consist of 518,319 ordinary shares held by David and Debora Goldfarb, of which 33,534 ordinary shares, calculated on a post-Reorganization basis, were issued on December 10, 2013 upon conversion of the Convertible Security Notes and 174,960 shares, calculated on a post-Reorganization basis, were issued on December 22, 2013 upon the conversion of the Bridge Loans and the Convertible Loan Agreement. According to the Shareholders Rights Agreement, any ordinary shares held by Mr. and Mrs. Goldfarb and Medgal Holdings S.A. are to be aggregated for the purpose of determining the eligibility of the parties with respect to any rights granted to major shareholders under our articles of association in effect prior to the offering. Each such shareholder is exercising the voting and/or disposition powers on its respective shares separately. The Shareholders Rights Agreement will terminate upon the completion of the offering. For more information see Certain Relationship and Related Party Transactions Shareholders Rights Agreement.

(5) Ordinary shares beneficially owned consist of 343,438 ordinary shares held by Medgal Holdings S.A., a company incorporated under the law of Panama, of which 20,412 ordinary shares, calculated on a post-Reorganization basis, were issued on December 10, 2023 upon conversion of the Convertible Security Notes and 104,976 shares, calculated on a post-Reorganization basis, were issued on December 22, 2013 upon the conversion of the Bridge Loans and the Convertible Loan Agreement, and 33,613 ordinary shares were issued on February 3, 2013, pursuant to the Share Purchase Agreement. According to the Shareholders Rights Agreement, any ordinary shares held by David and Debora Goldfarb and Medgal Holdings S.A. are to be aggregated for the purpose of determining the eligibility of the parties to any rights granted to major shareholders under our articles of association in effect prior to the offering. Each such shareholder is exercising the voting and/or disposition powers on its respective shares separately. Mrs. Daniela Abadi Eskenazi is the natural person exercising the voting and/or disposition powers on the shares owned by Medgal Holdings S.A. The Shareholders Rights Agreement will terminate upon the completion of the offering. See Certain Relationship and Related Party Transactions Shareholders Rights Agreement.

(6) Ordinary shares beneficially owned consist of (i) options to purchase 8,583 shares that are currently exercisable or will be exercisable within 60 days from the date hereof, all of which have an exercise price per share of $3.57, will

expire in September 2023 and were granted on February 21, 2014, and (ii) 41,438 ordinary shares held through Tushia Consulting Engineers Ltd., of which Shmuel Nir is its controlling shareholder, holding substantially all of the voting power, of which 21,870 ordinary shares,

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calculated on a post-Reorganization basis, were issued in 2000, 14,580 ordinary shares, calculated on a post-Reorganization basis, were issued in 2008 upon the conversions of certain bridge loans, 2,187 ordinary shares, calculated on a post-Reorganization basis, were issued on December 22, 2013 upon the conversion of the Convertible Loan Agreement, and 2,801 ordinary shares were issued pursuant to the Share Purchase Agreement, dated February 3, 2014.

(7) Will serve as a director upon completion of the offering.

This table is based upon information supplied by officers, directors and principal shareholders and is believed to be accurate. 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 shareholder s address is: c/o Galmed Pharmaceuticals Ltd., 8 Shaul Hamelech Blvd., Amot Hamishpat Bldg., Tel Aviv, Israel 64733.

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DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our Articles, which will be adopted immediately prior to the consummation of this offering, are summaries and do not purport to be complete and are qualified in their entirety by the complete text of the Articles, which will be attached as an exhibit to this registration statement on Form F-1 pursuant to an amendment hereto.

Share Capital

Our number with the Israeli Registrar of Companies is 514953512. Our purpose is set forth in Section 2 of our Articles and includes every lawful purpose.

On December 31, 2012, the registered capital of our predecessor, GHI, was $50,000 divided into 50,000 shares, $1.00 par value per share. The amount of issued and outstanding ordinary shares of GHI as of December 31, 2012 was 6,853 ordinary shares. All issued and outstanding ordinary shares are fully paid and non-assessable. In addition, as of December 31, 2012, GHI had 384 shares issuable upon the exercise of options.

On July 31, 2013, the Company s incorporation date, the registered capital of the Company was NIS 500,000 divided into 50,000,000 ordinary shares, NIS 0.01 par value per share.

On December 31, 2013, the registered capital of our predecessor, GHI, was $50,000 divided into 50,000 shares, $1.00 par value per share. The amount of issued and outstanding ordinary shares of the GHI as of December 31, 2013 was 9,739. All issued and outstanding ordinary shares are fully paid and non-assessable. In addition, as of December 31, 2013, we had 2,057 shares issuable upon the exercise of options. These issued options had a weighted average exercise price of $822.80 per share.

On December 31, 2013, assuming that the completion of the Reorganization occurred as of such date, the registered capital of the Company was NIS 500,000 divided into 50,000,000 ordinary shares, NIS 0.01 par value per share. Also assuming that the completion of the Reorganization occurred as of December 31, 2013, the amount of issued and outstanding ordinary shares of the Company as of such date was 7,099,731. All issued and outstanding ordinary shares are fully paid and non-assessable. In addition, as of December 31, 2013 and assuming that the completion of the Reorganization occurred as of such date, we have 1,460,916 shares issuable upon the exercise of options outstanding under our 2013 Plan, 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and 39,084 ordinary shares reserved for future grants under our 2013 Plan. These issued options have a weighted average exercise price of $1.13 per share and expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering, and the option to purchase 38,637 shares granted to a service provider, which has no expiration date.

Following the completion of the Reorganization, on February 27, 2014, the amount of issued and outstanding ordinary shares of the Company was 7,659,955, which such amount includes 560,224 ordinary shares issued pursuant to the Share Purchase Agreement, dated February 3, 2014. All issued and outstanding ordinary shares are fully paid and non-assessable. In addition, as of February 27, 2014, we had 1,539,472 shares issuable upon the exercise of options outstanding under our 2013 Plan, 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and 784,304 ordinary shares reserved for future grants under our 2013 Plan. These issued options have a weighted average exercise price of $1.13 per share and expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering. On

February 27, 2014, we also had 38,637 shares issuable upon the exercise of a certain option granted to a service provider that is not subject to our 2013 Plan and which has no expiration date.

Share Issuances

On December 10, 2013, all Convertible Security Notes were converted by their respective holders into 707 shares of GHI at a conversion price of $2,601.41 per share, of which 77 shares were issued to G. Yarom Medical Research Ltd. and 58 shares were issued to Shirat HaChaim Ltd. See Certain Relationships and Related Party Transactions above. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to such shareholders 515,403 of our ordinary shares, which shares represent the same

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percentage of our share capital as such 707 shares represented of the share capital of GHI, and of which 56,133 ordinary shares were issued to G. Yarom Medical Research Ltd. and 42,282 shares were issued to Shirat HaChaim Ltd.

On December 22, 2013, all outstanding amounts under the Bridge Loans and the Convertible Loan Agreement were converted into 2,133 shares of GHI, of which 38 shares were issued to G. Yarom Medical Research Ltd., and 961 shares were issued to Shirat HaChaim Ltd. See Certain Relationships and Related Party Transactions above. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to all such shareholders 1,554,957 ordinary shares, which shares represent the same percentage of our share capital as such 2,133 shares represented of the share capital of GHI, and of which 700,569 shares were issued to Shirat HaChaim Ltd. and 27,702 shares were issued to G. Yarom Medical Research Ltd.

In December 2013, our predecessor, GHI, granted our officers, directors and consultants options to purchase 1,673 shares in consideration of services provided by such officers, directors and consultants. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, in December 2013, we granted our officers, directors and consultants options to purchase 1,499,553 of our ordinary shares, of which 1,331,640 are fully vested and the remaining will vest over a period of two years and upon the other terms and conditions set forth in our 2013 Plan and the respective option agreements. The weighted average exercise price of such issued options is $1.13 per share and each will expire in September 2023, with the exception of the Warrant, which will be exercised automatically upon the completion of this offering, and the option to purchase 38,637 shares granted to the service provider, which has no expiration date. These options represent the same percentage of our share capital as the options such officers and directors hold in GHI represent of the share capital of GHI.

On December 31, 2013, our predecessor, GHI, issued 46 ordinary shares of GHI to Shirat HaChaim Ltd. pursuant to a share purchase agreement. See Certain Relationships and Related Party Transactions above. In connection with the Reorganization, and in accordance with the Tax Pre-Ruling, we issued to such shareholder 33,534 of our ordinary shares, which shares represent the same percentage of our share capital as such 46 ordinary shares represent of the share capital of GHI.

On February 3, 2014, pursuant to the Share Purchase Agreement, we issued 560,224 of our ordinary shares to certain existing shareholders and new investors at a price per share of $3.57, for a total investment amount of $2.0 million. See Certain Relationships and Related Party Transactions above.

Holders of ordinary shares have one vote for each ordinary share held on all matters to be voted on by shareholders, including the election of directors. Ordinary shares do not entitle their holders to preemptive rights. The Articles and Israeli law do not restrict in any way the ownership or voting of ordinary shares by non-residents or persons who are not citizens of Israel, except with respect to subjects of nations which are in a state of war with Israel.

Subject to the rights of holders of shares with preferential rights (which may be issued in the future), holders of paid up ordinary shares are entitled to participate in the payment of dividends and, in the event of a winding-up of the Company, in the distribution of assets available for distribution, in proportion to the amount paid up or credited as paid up on account of the nominal value of the shares held by them respectively and in respect of which such dividend is being paid or such distribution is being made, without considering any premium those holders might have paid in excess of that nominal value.

Shares with preferential rights relating, among other things, to dividends, voting and repayment of share capital can be created by adoption of a resolution of the shareholders at a general meeting of shareholders at which a quorum is present, by a simple majority of the voting power represented at the meeting in person or by proxy and voting thereon.

The Company can similarly subdivide issued and outstanding ordinary shares. Modification or abrogation of the rights of any class of shares requires the written consent of the holders of 75% of the issued shares of such a class or adoption of a resolution passed by a simple majority of those present in person or by proxy and voting at a separate general meeting of the holders of the shares of that class.

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Election of Directors

The Board consists of three classes of directors (not including external directors who do not form part of any class), with one class being elected each year by shareholders at the Company s annual general meeting for a term of approximately three years. In accordance with our Articles, directors so elected cannot be removed from office by the shareholders until the expiration of their term of office. Ordinary shares do not have cumulative voting rights. As a result, the holders of ordinary shares that represent a simple majority of the voting power represented at a shareholders meeting and voting at the meeting have the power to elect all of the directors put forward for election, subject to specific requirements under the Companies Law with respect to the election of external directors.

Share Certificates

Ordinary share certificates registered in the names of two or more persons are deliverable to the person first named in the share register and such delivery shall be deemed sufficient delivery to all co-owners. If two or more such persons tender a vote, the vote of the person whose name first appears in the share register will be accepted to the exclusion of any other. Notices may be given only to the person whose name first appears in the register. If two or more persons jointly hold or are entitled to a share, any one of them may give effectual receipt for any dividend payable or property distributable in respect of such share.

Dividends and Dividend Policy

Dividends may be distributed only out of profits available for dividends as determined by the Companies Law, provided that there is no reasonable concern that the distribution will prevent the Company from being able to meet its existing and anticipated obligations when they become due. Generally, under the Companies Law, the decision to distribute dividends and the amount to be distributed is made by a company s board of directors. The Articles provide that the Board may from time to time declare, and cause the Company to pay, such dividends as may appear to it to be justified by the profits of the Company and that the Board has the authority to determine the time for payment of such dividends and the record date for determining the shareholders entitled to receive such dividends, provided the date is not before the date of the resolution to distribute the dividend. Declaration of dividends does not require shareholder approval.

Pursuant to the Settlement with Prof. Gilat s beneficiaries, we have agreed not to distribute any dividends to our shareholders until the amount of the Settlement, including interest thereon, is paid in full. See above, under Management Employment Agreements and Arrangements with Directors and Related Parties Confirmation and Release Letter from the Beneficiaries of the Late Professor Tuvia Gilat.

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 and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board may deem relevant.

Payment of dividends may also be subject to Israeli withholding taxes. See Taxation Israeli Tax Considerations for additional information.

Transfer of Shares

Ordinary shares which have been fully paid-up are transferable by submission of a proper instrument of transfer to the Company or its transfer agent together with the certificate of the shares to be transferred and such other evidence, if any, as the directors may require to prove the rights of the intending transferor in the transferred shares.

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our Articles, 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 Articles 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.

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Shareholder Meetings

The Articles provide that an annual general meeting must be held at least once in every calendar year, not later than 15 months after the last preceding annual general meeting, at such time and place as may be determined by the Board. The Board may, in its discretion, convene additional shareholder meetings and, pursuant to the Companies Law, must convene a meeting upon the demand of two directors or one quarter of the directors in office or upon the demand of the holder or holders of 5% of the Company s issued share capital and 1% of its voting rights or upon the demand of the holder or holders of 5% of its voting rights. All demands for shareholder meetings must set forth the items to be considered at that meeting. Pursuant to the Companies Law, the holder or holders of 1% of the Company s voting rights may request the inclusion of an item on the agenda of a future shareholder meeting, provided the item is appropriate for discussion at a shareholder meeting. The agenda for a shareholder meeting is determined by the Board and must include matters in respect of which the convening of a shareholder meeting was demanded and any matter requested to be included by holder(s) of 1% of the Company s voting rights, as detailed above.

Pursuant to the Companies Law and regulations promulgated thereunder with respect to the convening of general meetings in a public company, shareholder meetings generally require prior notice of not less than 21 days, and for certain matters specified in the Companies Law, not less than 35 days. The function of the annual general meeting is to elect directors in accordance with the Articles, receive and consider the profit and loss account, the balance sheet and the ordinary reports and accounts of the directors and auditors, appoint auditors and fix their remuneration and transact any other business which under the Articles or applicable law may be transacted by the shareholders of a company in general meeting.

The quorum required for either an annual (regular) or an extraordinary (special) general meeting of shareholders consists of at least two shareholders present in person or by proxy holding shares comprising in the aggregate more than 33% of the voting rights of the Company. If a meeting is convened by the Board upon the demand of shareholders or upon the demand of less than 50% of the directors then in office or directly by such shareholders or directors and no quorum is present within half an hour from the time appointed, it shall be cancelled. If a meeting is otherwise called and no quorum is present within such time, the meeting is adjourned to the same day one week later at the same time and place or at such other time and place as the Board may determine and specify in the notice of the general meeting and it shall not be necessary to give notice of such adjournment. If a quorum is not present within half an hour from the time stated for such adjourned meeting, any shareholders present in person or by proxy at such meeting shall constitute a quorum. Generally, under the Companies Law and the Articles, shareholder resolutions are deemed adopted if approved by the holders of a simple majority of the voting rights represented at a meeting and voting unless a different majority is required by law or pursuant to the Articles. The Companies Law provides that resolutions on certain matters, such as amending a company s articles of association, assuming the authority of the board of directors in certain circumstances, appointing auditors, appointing external directors, approving certain transactions, increasing or decreasing the registered share capital and approving most mergers must be made by the shareholders at a general meeting. A company may determine in its articles of association certain additional matters in respect of which resolutions by the shareholders in a general meeting will be required.

Mergers and Acquisitions under Israeli Law

Merger

Under the Companies Law, a merger is generally required to be approved by the shareholders and board of directors of each of the merging companies. If the share capital of the company that will not be the surviving company is

divided into different classes of shares, the approval of each class is also required, unless determined otherwise by the court. Similarly, unless the court determines differently, a merger will not be approved if it is objected to by shareholders holding a majority of the voting rights participating and voting at the meeting, after excluding the shares held by the other party to the merger, by any person who holds 25% or more of the other party to the merger or by anyone on their behalf, including by the relatives of or corporations controlled by these persons. 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

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to the merger. Also, a merger can be completed only after all approvals have been submitted to the Israeli Registrar of Companies and 30 days have passed from the time that shareholder resolutions were adopted in each of the merging companies and 50 days have passed from the time that a proposal for approval of the merger was filed with the Israeli Registrar of Companies.

Special Tender Offer

The Companies Law also provides that, subject to certain exceptions, 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 would become a holder of 25% or more of the voting power at general meetings. This rule does not apply if there is already another holder of 25% or more of the voting power at general meetings. Similarly, the Companies Law provides that, subject to certain exceptions, 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 would become a holder of more than 45% of the voting power of the company. This rule does not apply if someone else already holds more than 45% of the voting power of the company. According to regulations enacted pursuant to the Companies Law, these tender offer requirements may not apply to companies whose shares are listed for trading outside of Israel if, among other things, under local law or the rules of the stock exchange on which their shares are traded, there is a limitation on the percentage of control which may be acquired or the purchaser is required to make a tender offer to the public. However, the Israel Securities Authority s view is that the above referenced leniency will not apply with respect to companies whose shares are listed on exchanges in the United States, including on the Nasdaq Capital Market, and that the tender offer requirements will apply to such companies.

Full Tender Offer

Under the Companies Law, a person may not acquire shares in a public company if, after the acquisition, he will hold more than 90% of the shares or more than 90% of any class of shares of that company, unless a tender offer is made to purchase all of the shares or all of the shares of the particular class. The Companies Law also provides (subject to certain exceptions with respect to shareholders who held more than 90% of a company s shares or of a class of its shares as of February 1, 2000) that as long as a shareholder in a public company holds more than 90% of the company s shares or of a class of shares, that shareholder shall be precluded from purchasing any additional shares. In order that all of the shares that the purchaser offered to purchase be transferred to him by operation of law, one of the following must have occurred: (i) the shareholders who declined or do not respond to the tender offer hold less than 5% of the company s outstanding share capital or of the relevant class of shares and the majority of offerees who do not have a personal interest in accepting the tender offer accepted the offer or (ii) the shareholders who declined or do not respond to the tender offer hold less than 2% of the company s outstanding share capital or of the relevant class of shares.

A shareholder that had his or her shares so transferred, whether he or she accepted the tender offer or not, has the right, within six months from the date of acceptance of the tender offer, to petition the court to determine that the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, the purchaser may provide in its offer that shareholders who accept the tender offer will not be entitled to such rights.

If the conditions set forth above are not met, the purchaser may not acquire additional shares of the company from shareholders who accepted the tender offer to the extent that following such acquisition, the purchaser would own more than 90% of the company s issued and outstanding share capital.

The above restrictions apply, in addition to the acquisition of shares, to the acquisition of voting power.

Anti-takeover Measures under Israeli Law

The 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 Articles. 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

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value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our Articles, which requires the prior approval of the holders of a majority of the voting power of our issued and outstanding shares at a general meeting of shareholders. The convening of the general 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 Articles and the Companies Law as described above in Shareholder Meetings.

Also, we have not adopted a rights plan, also known as a poison pill. The legality of such rights plans as an additional anti-takeover measure has not been determined by the courts in Israel.

In addition, certain provisions of the Articles may have the effect of rendering more difficult or discouraging an acquisition of the Company deemed undesirable by the Board. Those provisions include: (i) limiting the ability of the Company s shareholders to convene general meetings of the Company (as discussed above); (ii) controlling procedures for the conduct of shareholder and Board meetings, including quorum and voting requirements; and (iii) the election and removal of directors. Moreover, the classification of the Board into three classes with terms of approximately three years each, and the requirement under Companies Law to have at least two external directors, who cannot readily be removed from office, may make it more difficult for shareholders who oppose the policies of the Board to remove a majority of the then current directors from office quickly. It may also, in some circumstances, together with the other provisions of the Articles and Israeli law, deter or delay potential future merger, acquisition, tender or takeover offers, proxy contests or changes in control or management of the Company, some of which could be deemed by certain shareholders to be in their best interests and which could affect the price some investors are willing to pay for ordinary shares.

Changes in Capital

Our Articles enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the 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 (under certain circumstances), require the approval of both our Board and an Israeli court.

Transfer Agent

Our transfer agent in the United States will be VStock Transfer, LLC.

Exchange Controls

There are no Israeli government laws, decrees or regulations that restrict or that affect our export or import of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, except for ownership by nationals of certain countries that are, or have been, in a state of war with Israel or otherwise as set forth under Taxation.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our ordinary shares. 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. Assuming that the underwriters do not exercise their over-allotment option with respect to this offering and assuming no exercise of options or warrants outstanding following the offering, we will have an aggregate of 10,674,843 ordinary shares outstanding upon completion of this offering. Of these shares, the Shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless purchased by affiliates (as that term is defined under Rule 144 of the Securities Act), who may sell only the volume of shares described below and whose sales would be subject to additional restrictions described below.

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 for the restrictions described below, and except for the lock-up restrictions described under Underwriting below. Further, substantially all of our outstanding shares will be subject to such lock-up agreements.

Rule 144

In general, if there are any restricted shares, under Rule 144 under the Securities Act, or Rule 144, as in effect on the date hereof, beginning 90 days after the date hereof, a person who holds restricted shares and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least six months, would be entitled to sell an unlimited number of our ordinary shares, provided current public information about us is available. In addition, under Rule 144, a person who holds restricted shares in us and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least one year, 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. Beginning 90 days after the date hereof, our affiliates who have beneficially owned our ordinary shares for at least six months are entitled to sell within any three month period a number of shares that does not exceed the greater of:

1% of the number of shares of our ordinary shares then outstanding, which will equal approximately ordinary shares immediately after this offering, assuming no exercise of the underwriter s over-allotment option; or
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; provided that current public information about us is available and the affiliate complies with the manner of sale requirements imposed by Rule 144.

Upon expiration of the lock-up restrictions described under Underwriting below, substantially all of our outstanding ordinary shares will either be unrestricted or will be eligible for sale under Rule 144, subject to Rule 144 volume limitations applicable to our affiliates. However, the sale of ordinary shares by our shareholders is further restricted and limited by the terms of the Tax Pre-Ruling which we have obtained from the Israeli Tax Authority in connection with our Reorganization, as detailed under Taxation Israeli Tax Considerations below. We cannot estimate the number of our ordinary shares that our existing shareholders will elect to sell.

Rule 701

In general, under Rule 701 of the Securities Act, or Rule 701, as currently in effect, each of our employees, consultants or advisors who purchased, or who purchases pursuant to an offer made prior to the date hereof, ordinary shares from us in connection with a compensatory share plan or other written agreement, if such purchase or offer, as applicable, was made in accordance with Rule 701, is eligible, beginning 90 days from the date hereof, to resell such shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144. We make no assurance that any such prior purchase or offer was made in accordance with Rule 701.

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Form S-8 Registration Statements

Following the completion of this offering, we may file one or more registration statements on Form S-8 under the Securities Act to register the ordinary shares issued or reserved for issuance under our 2013 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 the lock-up restrictions under Underwriting below, in which case, after the expiration of such lock-up, or by the terms of the Tax Pre-Ruling which we have obtained from the Israeli Tax Authority in connection with our Reorganization, as detailed under Taxation Israeli Tax Considerations below.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL SHARE TRANSFER RESTRICTION MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN LEGAL ADVISOR REGARDING THE PARTICULAR SECURITIES LAWS AND TRANSFER RESTRICTION CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR ORDINARY SHARES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

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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, including the 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 brief summary of the material Israeli income tax laws applicable to us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares. This summary does not discuss all the aspects of Israeli 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 investors 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 hereof and does not take into account possible future amendments which may be under consideration.

General Corporate Tax Structure in Israel

Israeli resident (as defined below) companies, such as the Company, are generally subject to corporate tax at the rate of 25% of their taxable income in 2013. As of January 1, 2014, the Israeli corporate tax rate will be 26.5%.

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

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, which we refer to as the Industry Encouragement Law, provides several tax benefits for Industrial Companies, which are defined as Israeli resident-companies of which 90% or more of their income in any tax year is derived from an Industrial Enterprise that it owns, or an enterprise whose principal activity in a given tax year is industrial production. Eligibility for benefits under the Industry Encouragement Law is not contingent upon approval of any governmental authority.

The following corporate tax benefits, among others, are available to Industrial Companies:

amortization over an eight year period of the cost of purchasing a patent, rights to use a patent and rights to know-how, which are used for the development or advancement of the company, commencing in the year in which such rights were first exercised;

under limited conditions, an election to file consolidated tax returns with related Industrial Companies; and

deductions of expenses related to a public offering in equal amounts over a three year period.

Currently, we are not qualified as an Industrial Company within the meaning of the Industry Encouragement Law, and there can be no assurance that we will qualify as an Industrial Company in the future or that, even if we qualify as an Industrial Company, the benefits described above will be available to us at all.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, which we refer to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets). The Investment Law was significantly amended effective April 1, 2005 and further amended as of January 1, 2011, or the 2011 Amendment. The 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment.

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Tax Benefits Under the 2011 Amendment

The 2011 Amendment canceled the availability of the benefits granted to Industrial Companies under the Investment Law prior to 2011 and, instead, introduced new benefits for income generated by a Preferred Company through its Preferred Enterprise (as such terms are defined in the Investment Law) as of January 1, 2011.

The definition of a Preferred Company includes a company incorporated in Israel that is not fully owned by a governmental entity, and that has, among other things, a Preferred Enterprise and is controlled and managed from Israel. Under the 2011 Amendment, a Preferred Company is entitled to a reduced corporate tax rate of 12.5% with respect to its income derived by its Preferred Enterprise in 2013 and 2014, unless the Preferred Enterprise is located in a specified development zone, in which case the rate will be 7.5%. However, under a recent amendment announced in August 2013, or the 2013 Amendment, beginning in 2014 and in each year thereafter, a Preferred Company may only be entitled to reduced corporate tax rates of 16% and 9%, respectively. Income derived by a Preferred Company from a Special Preferred Enterprise (as such term is defined in the Investment Law) would be entitled, during a benefit period of ten years, to further reduced tax rates of 8%, or 5% if the Special Preferred Enterprise is located in a certain development zone.

Dividends paid out of income attributed to a Preferred Enterprise are generally subject to withholding tax at source at the rate of 15% or such lower rate as may be provided in an applicable tax treaty. Under the 2013 Amendment, beginning in 2014, dividends paid out of income attributable to a Preferred Enterprise will be subject to a withholding tax rate of 20%. However, if such dividends are paid to an Israeli company, no tax is required to be withheld.

A Beneficiary Company may elect to file a notice until May 31st of each year in order to avail itself of the benefits of the 2011 Amendments to it pursuant to Sections 131 and 132 of the Income Tax Ordinance (New Version) 1961, referred to herein as the Israeli Tax Ordinance, and such benefits will apply on the tax year subsequent to the year in which such notice was filed.

Currently, we are not entitled to receive the tax benefits described above and there can be no assurance that we will be entitled to receive such benefits at any time in the future. Furthermore, there can be no assurance that even if in the future we meet the relevant requirements for such tax benefits, that such tax benefits will be available to us at all.

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.

Recently, the Israeli Parliament passed the Reduction of Deficit and Coping with Implications resulting from the Global Economic Crisis (Legislative Amendments), 2012, according to which an additional income tax at a rate of 2% will be imposed on high earners whose annual income or gains exceed NIS 811,560 beginning in 2013.

A Substantial Shareholder is generally a person who alone, or together with his or her relative or another person who collaborates with him or her on a regular basis, holds, directly or indirectly, at least 10% of any of the means of control of a 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), all regardless of the source of such right.

With respect to individuals, the term Israeli resident is generally defined under Israeli tax legislation as a person whose center of life is in Israel. The Israeli Tax Ordinance (as amended by Amendment Law No. 132 of 2002), states that in order to determine the center of life of an individual, consideration will be given to the individual s family, economic and social connections, including: (i) place of permanent residence; (ii) place of residential dwelling of the individual and the individual s immediate family; (iii) place of the individual s regular or permanent occupation or the place of his or her permanent employment; (iv) place of the

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individual s active and substantial economic interests; (v) place of the individual s activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (i) the individual was present in Israel for 183 days or more in the tax year; or (ii) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual s presence in Israel in that tax year and the two previous tax years is 425 days or more. Such presumption may be rebutted either by the individual or by the assessing officer.

Taxation of Israeli Resident Corporations on Payment of Dividends

Israeli resident corporations are generally exempt from Israeli corporate income tax with respect to dividends paid on ordinary shares held by such Israeli resident corporations as long as the profits out of which the dividends were paid were derived in Israel.

Capital Gains Taxes Applicable to Israeli Resident Shareholders

The income tax rate applicable to real capital gains derived by an Israeli individual resident from the sale of shares that were purchased after January 1, 2012, whether listed on a stock exchange or not, is 25%. However, if such shareholder is considered a Substantial Shareholder 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%. In addition, as noted above, an additional tax at a rate of 2% will be imposed on high earners whose annual income or gains exceed NIS 811,560 beginning in 2013.

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% beginning in 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 ordinary shares at the rate of 25% (or 30% for individuals, if such person is a Substantial Shareholder at the time he or she receives the dividend or on any date in the 12 months preceding such date), which tax will be withheld at source, unless a different rate is provided under an applicable tax treaty between Israel and the shareholder s country of residence.

A non-Israeli resident who has dividend income derived from or accrued in Israel, from which the full amount of tax was withheld at source, is generally exempt from the duty to file tax returns in Israel in respect of such income; provided that (i) such income was not derived from a business conducted in Israel by the taxpayer and (ii) 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, or 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 (as such term is defined in the Investment Law), 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 entirety 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 shareholders did not acquire their shares prior to January 1, 2009 and such gains were not derived from a permanent business 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.

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In addition, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the U.S.-Israel 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, or 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 183 days or more during the relevant taxable year; (ii) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of our voting power of the Company 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, subject to certain conditions. In any such case, the sale, exchange or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable. However, under the U.S.-Israel Tax Treaty, such Treaty U.S. Resident would be permitted to claim a credit for such taxes against U.S. federal income tax imposed on any gain from such sale, exchange or disposition, under the circumstances and subject to the limitations specified in the US-Israel Income Tax Treaty.

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.

Pre-Ruling Regarding a Reorganization of Our Corporate Structure

In connection with the Reorganization, as detailed under Business Historical Background and Corporate Structure above, we obtained a pre-ruling from the Israeli Tax Authority. The Tax Pre-Ruling confirms that the transfer of shares and assets resulting in the Company as the parent company and 100% equity-owner of GRD, which holds all the Group s intellectual property, including the Company s patent portfolio, GIL and GTTI, is not taxable pursuant to the provisions of the Israeli Tax Ordinance as long as certain requirements are met. Pursuant to the Tax Pre-Ruling, certain restrictions under the Israeli tax laws will apply to the Company and its subsidiaries, as well as to those shareholders and option holders and other holders of rights in the share capital of the Company (on a fully diluted basis), who participated in the Reorganization and held such rights immediately after the consummation of the Reorganization, or the Rights Holders. In this section, each of the terms Rights and/or share capital (on a fully diluted basis) includes shares, options to purchase shares and any other right in a body of persons as such term is defined in the Israeli Tax Ordinance. These restrictions generally restrict these entities and Rights Holders from making any disposition of their Rights in the transferred assets and shares for a two year period following the consummation of the Reorganization, or the Restriction Period. During the Restriction Period, these restrictions include the following:

- we may not sell or otherwise dispose of our intellectual property, other than out-licensing in the ordinary course of business;
- the Rights Holders immediately following the Reorganization must not change, subject to the following restriction and to the relief detailed below;
- the Rights Holders may not sell or otherwise transfer or dispose of more than 10% of their respective Rights, subject to the exemptions and relief detailed below;
- we must not sell or otherwise transfer or dispose of any of our shares in GTTI, GHI or GIL;

we may not deduct for tax purposes any expenses related to the Reorganization; and

during the two tax years following the end of the year in which the Reorganization was completed we may not offset losses (whether business or capital losses) incurred in the year in which the Reorganization was completed or in the years preceded that year up to the fair market value of the transferred asset.

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Notwithstanding the foregoing restrictions, so long as the aggregate holdings of the Rights Holders, collectively, is 51% or more of the total share capital of the Company (on a fully diluted basis), then at any time during the Restriction Period, the following changes described below might be permitted under the Israeli Tax Ordinance:

Sale of Shares or other Rights. One or more of the Rights Holders will be allowed to sell more than 10% of its Rights in the Company, subject to the following:

- other Rights Holders give their consent to such sale of Rights, which are in excess of the 10% aforementioned; and
- the aggregate number of ordinary shares and other Rights sold by all Rights Holders, collectively as a group, will not exceed 10% of the total Rights then-outstanding.

Public Offering. We may issue up to 49% of our share capital (on a fully-diluted basis) following such issuance in a public offering of our ordinary shares involving the listing of such shares on a securities exchange, including this offering and the listing of our ordinary shares on the Nasdaq Capital Market.

Private Placement. We may issue securities in a private placement to a person(s) who did not hold Rights in the company prior to such issuance, or a New Investor, provided that such private placement either (i) is in an amount which does not exceed 20% of our total share capital (on a fully-diluted basis) then-outstanding following such issuance in one or more separate transactions or (ii) does not exceed, in the aggregate, 49% of our total share capital following such issuance, each New Investor will not receive more than 20% of our total share capital (on a fully-diluted basis) after such issuance and each New Investor does not participate in subsequent offerings or private placements, even if such New Investor purchased less than 20% in such preceding private placement.

If during the Restriction Period, we or the Rights Holders commit a Violation, the transfer of shares or other rights and/or assets in connection with the Reorganization will become subject to taxation based on the greater of the transferred assets fair market value on the day of such Violation or taxes that, but for the Tax Pre-Ruling, would be payable in connection with the transfer of such assets and shares at the time of the Reorganization linked to the Israeli consumer price index linkage differentials and interest from the day of the actual transfer of such assets and shares until the day of payment of such taxes, unless the Israeli Tax Authority is satisfied that such Violation was a result of special circumstances beyond our control.

The foregoing restrictions do not apply to any sale of company securities issued after the date of the Tax Pre-Ruling to new investors who are not Rights Holders, including our ordinary shares issued to new investors who are not Rights Holders pursuant to the Share Purchase Agreement and the Shares issued in connection with this offering.

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 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

Certain U.S. Federal Income Tax Consequences

The following is a general summary of what we believe to be certain 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 our ordinary shares pursuant to the offering and hold such ordinary shares as capital assets. This summary is based on the Internal Revenue Code (the Code), the regulations of the U.S. Department of the Treasury issued pursuant to the Code (the Treasury Regulations), the income tax treaty between the United States and Israel (the

U.S.-Israel Tax Treaty), and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with

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retroactive effect, or to different interpretation. No ruling has been sought from the IRS with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This summary is no substitute for consultation by prospective Investors with their own tax advisors. This summary does not address all of the tax considerations 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 (including, without limitation, banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire our ordinary shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons who acquire our ordinary shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, persons that have a functional currency other than the U.S. dollar, persons that own (or are deemed to own, indirectly, or by attribution) 10% or more of our shares, or persons that mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift or alternative minimum tax considerations, or any U.S. federal tax consequences other than U.S. federal income tax consequences.

As used in this summary, the term U.S. Holder means a beneficial owner of our ordinary shares that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable 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 with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or that has a valid election in effect under applicable Treasury Regulations to be treated as a United States person.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares, the tax treatment of such partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of our ordinary shares.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Holders. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Holders

The discussions under Distributions and under Sale, Exchange or Other Disposition of Ordinary Shares below assume that we will not be treated as a PFIC for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC in 2013 or any subsequent year, and it is possible that we will be a PFIC in 2013 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under Passive Foreign Investment Company.

Distributions. Subject to the discussion below under Passive Foreign Investment Company, 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). Any distributions in excess of our earnings and profits will be applied against and will reduce (but not below zero) the U.S. Holder s tax basis in its ordinary shares, and, to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of our ordinary shares.

If we were to pay dividends, we expect to pay such dividends in NIS. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Holder s income as a U.S. dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Holder generally will not recognize a foreign currency gain or loss. However, if the

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U.S. Holder converts the NIS into U.S. dollars on a later date, the U.S. Holder must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss will generally be ordinary income or loss and will be U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the U.S.-Israel Tax Treaty, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Holder may be credited against the U.S. Holder s U.S. federal income tax liability or, alternatively, may be deducted from the U.S. Holder s taxable income. The election to deduct, rather than credit, foreign taxes, is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Holder or withheld from 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 or, in the case of some U.S. Holders, as general category income for U.S. foreign tax credit purposes. Because the rules governing foreign tax credits are complex, U.S. Holders should consult their own tax advisors regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares will not be eligible for the dividends-received deduction generally allowed to corporate U.S. Holders with respect to dividends received from U.S. corporations.

For taxable years beginning on or after January 1, 2013, certain distributions treated as dividends that are received by an individual U.S. Holder from a qualified foreign corporation generally qualify for a 20% reduced maximum tax rate so long as certain holding period and other requirements are met. A non-U.S. corporation (other than a corporation that is treated as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. Dividends paid by us in a taxable year in which we are not a PFIC and with respect to which we were not a PFIC in the preceding taxable year are expected to be eligible for the 20% reduced maximum tax rate, although we can offer no assurances in this regard. However, any dividend paid by us in a taxable year in which we are a PFIC or were a PFIC in the preceding taxable year will be subject to tax at regular ordinary income rates (along with any applicable additional PFIC tax liability, as discussed below). As noted above, we have not determined whether we are currently a PFIC or not or whether we will be a PFIC or not.

The additional 3.8% net investment income tax (described below) may apply to dividends received by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

Sale, Exchange or Other Disposition of Ordinary Shares. Subject to the discussion under Passive Foreign Investment Company below, a U.S. Holder generally will recognize capital gain or loss upon the sale, exchange, or other disposition of our ordinary shares in an amount equal to the difference between the amount realized on the sale, exchange, or other disposition and the U.S. Holder s adjusted tax basis in such ordinary shares. This capital gain or loss will be long-term capital gain or loss if the U.S. Holder s holding period in our ordinary shares exceeds one year. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 20% for taxable years beginning on or after January 1, 2013) will apply to individual U.S. Holders. The deductibility of capital losses is subject to limitations. The gain or loss will generally be income or loss from sources within the United States for U.S. foreign tax credit purposes, subject to certain possible exceptions under the U.S.-Israel Tax Treaty. The additional 3.8% net investment income tax (described below) may apply to gains recognized upon the sale, exchange, or other taxable

disposition of our ordinary shares by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

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Passive Foreign Investment Company

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

A foreign corporation s PFIC status is an annual determination that is based on tests that are factual in nature, and our status for any year will depend on our income, assets, and activities for such year. We have not determined whether we have previously been a PFIC or will be a PFIC in 2013 or in future years. Because the PFIC determination is highly fact intensive, there can be no assurance that we will not be a PFIC in 2013 or any other year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS or a court will agree with our conclusion.

U.S. Holders should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Holder is subject to different rules depending on whether the U.S. Holder makes an election to treat us as a qualified electing fund, referred to herein as a QEF election, for the first taxable year that the U.S. Holder holds ordinary shares makes a mark-to-market election with respect to the ordinary shares, or makes neither election. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election.

QEF Election. One way in which certain of the adverse consequences of PFIC status can be mitigated is for a U.S. Holder to make a QEF election. Generally, a shareholder making the QEF election is required for each taxable year to include in income a pro rata share of the ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election.

Mark-to-Market Election. Alternatively, if our ordinary shares are treated as marketable stock, a U.S. Holder would be allowed to make a mark-to-market election with respect to our ordinary shares, provided the U.S. Holder completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Holder generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of our ordinary shares at the end of the taxable year over such holder s adjusted tax basis in such ordinary shares. The U.S. Holder would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Holder s adjusted tax basis in our ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Holder s tax basis in our ordinary shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary loss to the extent that such loss

does not exceed the net mark-to-market gains previously included in income by the U.S. Holder, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is regularly traded on a qualified exchange within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange

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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. To be marketable stock, our ordinary shares must be regularly traded on a qualifying exchange (i) in the United States that is registered with the SEC or a national market system established pursuant to the Exchange Act or (ii) outside the United States that is properly regulated and meets certain trading, listing, financial disclosure and other requirements. Our ordinary shares are expected to constitute marketable stock as long as they remain listed on the Nasdaq Capital Market and are regularly traded.

A mark-to-market election will not apply to our ordinary shares held by a U.S. Holder 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 PFIC subsidiary that we own. Each U.S. Holder is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares.

Each U.S. Holder should consult its own tax adviser with respect to the applicability of the net investment income tax (discussed below) where a mark-to-market election is in effect.

Default PFIC Rules. A U.S. Holder who does not make a timely QEF election (we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a QEF election) or a mark-to-market election, referred to in this summary as a Non-Electing U.S. Holder, will be subject to special rules with respect to (i) any excess distribution (generally, the portion of any distributions received by the Non-Electing U.S. Holder on the ordinary shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Holder in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Holder s holding period for the ordinary shares), and (ii) any gain realized on the sale or other disposition of such ordinary shares. Under these rules:

the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Holder s holding period for such ordinary shares;
the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Holder who is an individual dies while owning our ordinary shares, the Non-Electing U.S. Holder s successor would be ineligible to receive a step-up in tax basis of such ordinary shares. Non-Electing U.S. Holders should consult their tax advisors regarding the application of the net investment income tax (described below) to their specific situation.

To the extent a distribution on our ordinary shares does not constitute an excess distribution to a Non-Electing U.S. Holder, such Non-Electing U.S. Holder generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under Taxation of U.S. Holders Distributions. Each U.S. Holder is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Holder, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Holder is treated as a direct or indirect Non-Electing U.S. Holder even if we are not a PFIC for such years. A U.S. Holder is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the deemed sale election of Code Section 1298(b)(1) (which will be taxed under the adverse tax rules described above).

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. If we are classified as a PFIC, under attribution rules, U.S. Holders will be subject to the PFIC rules

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with respect to their indirect ownership interests in such PFICs, such that a disposition of the ordinary shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such ordinary shares or the deemed receipt of such distribution by the U.S. Holder, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Holder will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Holder is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

In addition, U.S. Holders should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of ordinary shares in a PFIC, including IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund).

The U.S. federal income tax rules relating to PFICs, QEF elections, and mark-to market elections are complex. U.S. Holders are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of our ordinary shares, any elections available with respect to such ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of our ordinary shares.

Certain Reporting Requirements

Certain U.S. Holders are required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, and certain U.S. Holders may be required to file IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Holder and us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply.

In addition, recently enacted legislation requires certain U.S. Holders to report information on IRS Form 8938, Statement of Specified Foreign Financial Assets, with respect to their investments in certain foreign financial assets, which would include an investment in our ordinary shares, to the IRS.

U.S. Holders who fail to report required information could become subject to substantial penalties. U.S. Holders should consult their tax advisors regarding the possible implications of these reporting requirements arising from their investment in our ordinary shares.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or proceeds on the disposition of our ordinary shares paid within the United States (and, in certain cases, outside the United States) to U.S. Holders other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently at 28%) may apply to such amounts if the U.S. Holder fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Holders who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Holder s U.S. federal income tax liability and such U.S. Holder may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS and furnishing any required

information in a timely manner.

New Legislative Developments

With respect to taxable years beginning on or after January 1, 2013, certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare surtax, or net investment income tax, on unearned income. For individuals, the additional net investment income tax applies to the lesser of (i) net investment income or (ii) the excess of modified adjusted gross income over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). Net investment income generally equals the taxpayer s gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes, among other things, passive income such as interest, dividends,

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annuities, royalties, rents, and capital gains. U.S. Holders are urged to consult their own tax advisors regarding the implications of the additional net investment income tax resulting from their ownership and disposition of our 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 RELATING TO THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES IN LIGHT OF THE INVESTOR S OWN CIRCUMSTANCES.

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UNDERWRITING

We have entered into an underwriting agreement, or the Underwriting Agreement, with Maxim Group LLC, or Maxim, acting as the sole book-runner and lead managing underwriter, with respect to the Shares subject to this offering. Subject to the terms and conditions of the Underwriting Agreement, the underwriters named below have agreed to purchase, and we have agreed to sell to them, the number of Shares provided below opposite its name.

Underwriters	Number of Shares
Maxim Group LLC	2,482,725
MLV & Co. LLC	212,805
Feltl and Company, Inc.	141,870
Total	2,837,400

The underwriters are offering the Shares, subject to acceptance of the Shares from us and subject to prior sale. The Underwriting Agreement provides that the obligations of the underwriters to pay for and accept delivery of the Shares offered by this prospectus are subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the Shares if any such securities are taken, other than those Shares covered by the over-allotment option described below.

Overallotment

The Underwriting Agreement provides that the Company will grant to Maxim an option, exercisable within 45 days after the closing of this offering, to acquire up to an additional 425,610 Shares, or 15% of the total number of Shares to be offered by the Company pursuant to this offering, solely for the purpose of covering over-allotments.

Commission and Expenses

Maxim has advised us that the underwriters propose to offer the Shares to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.10 per Share. The underwriters may allow, and certain dealers may re-allow, a discount from the concession not in excess of $0.10 per Share to certain brokers and dealers. After this offering, the initial public offering price, concession and reallowance to dealers may be reduced by Maxim. No such reduction shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The Shares are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part. Maxim has informed us that the underwriters do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discounts and commissions payable to the underwriters by us in connection with this offering.

	Fee Per Share[1]	Total Without Exercise of Over-Allotment	Total With Exercise of Over-Allotment
Public offering price	$ 13.50	$ 38,304,900	$ 44,050,635

Discount	$ 0.945	$ 2,681,343	$ 3,083,544

(1) The fees do not include the underwriter warrants or expense reimbursement as described below.

We have agreed to reimburse Maxim for certain out-of-pocket expenses it incurs in connection with this offering, including, but not limited to, filing offering materials with FINRA, any lucite memorabilia to be acquired by the underwriters in connection with this offering, background checks, road show expenses, costs of book-building, prospectus tracking and compliance software and the fees and disbursements of its counsel, accountants and other agents and representatives, up to a maximum aggregate of $100,000. Of such amount, we paid a $25,000 advance to Maxim s counsel, which will be applied against the anticipated legal expenses incurred by Maxim in connection with this offering.

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We estimate that expenses payable by us in connection with the offering of our Shares, other than the underwriting discounts and commissions and the counsel fees and disbursement reimbursement provisions referred to above, will be approximately $1,138,358.01.

Upon the closing of the offering, if, and only if, we raise a minimum of $20,000,000 at a pre-money valuation of at least $80,000,000 (including all ordinary shares, options, warrants and convertible securities on an as-exercised or as-converted basis, as the case may be), Maxim will have the right of first refusal to act as a manager or placement agent on customary terms for such transactions and with at least 20% of the economics for each and every public or private equity debt offering of the Company, or any successor to or any subsidiary of the Company, that takes place within a period of 12 months from the effective date of this registration statement. This right of first refusal will not apply to any financing provided by or solicited from any person or entity who is a current holder of our debt or equity.

We have also agreed to issue to Maxim or its designees, at the closing of this offering, warrants, or the Representative s Warrants, to purchase that number of our ordinary shares equal to up to 2% of the aggregate number of Shares sold in the offering. The Representative s Warrants will be exercisable at any time and from time to time, in whole or in part, during a period commencing six months from the effective date of this prospectus and will expire three years after such date. The Representative s Warrants will be exercisable at a price equal to 125.0% of the public offering price of the Shares in connection with the offering. The Representative s Warrants and the ordinary shares underlying the Representative s Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. Maxim or permitted assignees under the Rule will not sell, transfer, assign, pledge or hypothecate the Representative s Warrants or the ordinary shares underlying the Representative s Warrants, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representative s Warrants or the ordinary shares underlying the Representative s Warrants for a period of 180 days from the effective date of the registration statement, except that they may be assigned, in whole or in part, as specifically set forth in the Underwriting Agreement. The Representative s Warrants will provide for cashless exercise, piggyback registration rights for three years from the effective date of the registration statement and customary anti-dilution provisions (for share dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the Underwriting Agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

Officers, directors and shareholders of the Company holding an aggregate of 8,511,150 of our ordinary shares prior to the offering, have agreed to a 180 day lock-up period from the closing of this offering of the Shares with respect to the ordinary shares that they beneficially own, including the issuance of shares upon the exercise of convertible securities and options that are currently outstanding or which may be issued. This means that, for a period of 180 days following the closing of the offering of the Shares, such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Maxim.

The 180 day restricted period is subject to extension if (1) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (2) prior to the expiration of the restricted period, we announce that we will release earnings results during the 15 day period beginning on the last day of the

restricted period, in which case the restrictions imposed in the lock-up agreements will continue to apply until the expiration of the 18 day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

Maxim has no present intention to waive or shorten the lock-up period; however, the terms of the lock-up agreements may be waived at its discretion. In determining whether to waive the terms of the lock-up agreements, Maxim may base its decision on its assessment of the relative strengths of the securities markets and companies similar to ours in general, and the trading pattern of, and demand for, our securities in general.

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In addition, the Underwriting Agreement provides that we will not, for a period of 180 days following the closing of the offering of the Shares, offer, sell or distribute any of our securities, without the prior written consent of Maxim.

Listing

The Shares have been approved for listing on the Nasdaq Capital Market under the symbol GLMD.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by Maxim or by its affiliates. Other than the prospectus in electronic format, the information on Maxim s website and any information contained in any other website maintained by it is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or Maxim in its capacity as an underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Over-allotment involves sales by the underwriters of Shares in excess of the number of Shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of Shares over-allotted by the underwriters is not greater than the number of Shares that may be purchased in the over-allotment option. In a naked short position, the number of Shares involved is greater than the number of Shares in the over-allotment option. Maxim may close out any covered short position by either exercising the over-allotment option and/or purchasing Shares in the open market.

Syndicate covering transactions involve purchases of Shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of Shares to close out the short position, Maxim will consider, among other things, the price of Shares available for purchase in the open market as compared to the price at which it may purchase Shares through the over-allotment option. If the underwriters sell more Shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying Shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the Shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit Maxim to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our Shares or preventing or retarding a decline in the market price of our securities. As a result, the price of our Shares may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our securities. In addition, neither we nor the underwriters make any representations that the underwriters will engage in these stabilizing transactions or that any transaction,

once commenced, will not be discontinued without notice.

No Prior Public Market

Prior to this offering, there has been no public market for our securities and the public offering price for our securities will be determined through negotiations between us and Maxim. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market

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valuations of other companies that we and Maxim believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which our Shares will trade in the public market subsequent to this offering or that an active trading market for our Shares will develop and continue after this offering.

Offers Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the Shares offered by this prospectus in any jurisdiction where action for that purpose is required. The Shares offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such Shares be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any Shares offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

European Economic Area

In relation to each Member State of the European Economic Area, or EEA, which has implemented the Prospectus Directive, or a Relevant Member State, an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are 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;

(b) to any legal entity which 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;

(c) by the underwriters to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive; provided that no such offer of securities shall result in a requirement for the publication by us or any representative of a prospectus pursuant to Article 3 of the Prospectus Directive.

Any person making or intending to make any offer of securities within the EEA should only do so in circumstances in which no obligation arises for us or any of the underwriters to produce a prospectus for such offer.

Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of securities through any financial intermediary, other than offers made by the underwriters which constitute the final offering of securities contemplated in this prospectus.

For the purposes of this provision, and your representation below, the expression an offer to the public in relation to any securities 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 any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

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Each person in a Relevant Member State who receives any communication in respect of, or who acquires any securities under, the offer of securities contemplated by this prospectus will be deemed to have represented, warranted and agreed to and with us and each underwriter that:

(A) it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and

(B) in the case of any securities acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the securities acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or (ii) where securities have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors, as defined in the Prospectus Directive, (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Israel

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

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;

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;

an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981;

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;

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;

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;

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;

an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968, acting on its own account;

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;

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entity fully owned by investors of the type listed in Section 15A(b) of the Securities Law, 5728-1968;
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
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 Section 15A(b)(1) of the Securities Law 1968 instead of as an eligible client for the meaning of this law).

Offerees of the Shares offered hereby, or the 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, or the Consent. An appeal to an Investor for the Consent shall not be considered a public offering. This prospectus 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, ninth, 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.

Canada

The Shares sold in this offering have not been and will not be qualified for distribution under applicable Canadian securities laws. Shares may be offered to residents of Canada pursuant to exemptions from the prospectus requirements of such laws.

Other Relationships

Maxim and its affiliates may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They may in the future receive customary fees and commissions for these transactions. Maxim did not provide any financing, investment and/or advisory services to us during the 180 day period preceding the filing of the registration statement related to this offering, and as of the date of this prospectus, other than as previously disclosed, we do not have any agreement or arrangement with Maxim to provide any of such services during the 90 day period following the effective date of the registration statement related to this offering.

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EXPENSES RELATED TO THE OFFERING

We estimate that the total expenses of this offering payable by us, excluding the underwriting discounts, commissions and expenses, will be approximately $1,238,358.01 as follows:

SEC Registration Fee	$5,847.76
FINRA Filing Fee	$7,310.25
Exchange Listing Fees	$55,000.00
Printing and Engraving Expenses	$40,000.00
Edgarizing Costs	$50,000.00
Transfer Agent Fees and Expenses	$200.00
Accounting Fees and Expenses	$160,000.00
Legal Fees and Expenses	$520,000.00
Miscellaneous	$400,000.00
Total	$1,238,358.01

All amounts in the table are estimates and subject to future contingencies, except the SEC registration fee, exchange listing fees and the FINRA filing fee.

The total underwriting discounts that we will be required to pay will be approximately $2,681,343 and $3,083,544, or 7% and 7%, of the gross proceeds of this offering, respectively, assuming full exercise of the over allotment option.

LEGAL MATTERS

The validity of the Shares being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Tulchinsky, Stern, Marciano, Cohen, Levitski & Co., Tel Aviv, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Greenberg Traurig, P.A, Miami, Florida. Certain legal matters in connection with this offering will be passed upon for the underwriters by Yigal Arnon & Co., Tel Aviv, Israel, with respect to Israeli law, and by Ellenoff Grossman & Schole LLP, New York, New York, with respect to U.S. law.

EXPERTS

The consolidated financial statements of Galmed Holdings Inc. and its subsidiaries as of December 31, 2013 and 2012 and for the years then ended and the audited balance sheet of Galmed Pharmaceuticals Ltd. as of December 31, 2013 included in this prospectus have been audited by Brightman Almagor Zohar & Co., a member firm of Deloitte Touche Tohmatsu Limited, an independent registered public accounting firm, as stated in their report, which is included herein. Such consolidated financial statements are included in reliance upon the authority of said firm given upon their authority as experts in accounting and auditing.

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 any Israeli experts named in this registration statement, most of whom reside outside of the United States,

may be difficult to obtain within the United States. Furthermore, because a majority of our assets and most of our directors and officers are located outside of the United States, any judgment obtained in the United States against us or certain of our directors and officers may be difficult to collect within the United States.

We have been informed by our legal counsel in Israel, Tulchinsky, Stern, Marciano, Cohen, Levitski & 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 is non-appealable, including a judgment based upon the civil liability provisions of the Securities Act or the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that, among other things:

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;
The judgment is final and is not subject to any right of appeal, and is executory in the state in which it was given;
The prevailing law of the foreign state in which the judgment was rendered allows for the enforcement of judgments of Israeli courts;
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 and arguments;
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;
The judgment was not obtained by fraud and does not conflict with any other valid judgments in the same matter between the same parties;
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
The judgment and the obligations imposed by the judgment are enforceable according to the laws of Israel and 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 constitutes the prospectus of Galmed Pharmaceuticals Ltd., filed as part of the registration statement, and it does not contain all information in the Registration Statement, as certain portions have been omitted in accordance with the rules and regulations of the SEC.

You may read and copy the registration statement and prospectus, 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*.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file 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 will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy

statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the

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Exchange Act with respect to their purchases and sales of ordinary shares. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. Although we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act, we intend to do so. As such, we will file with the SEC, within 90 days after the end of each fiscal year, or such other 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 within 45 days after the end of each of the first three fiscal quarters, or such other applicable time as required by the SEC, unaudited quarterly financial information on Form 6-K. However, in any event, as a foreign private issuer we are required by the SEC to file our annual report on Form 20-F within 120 days of our fiscal year's end or such other applicable time as required by the SEC. We also intend to furnish to the SEC under cover of Form 6-K certain other material information.

We expect to maintain a corporate website at *http://www.galmedpharma.com/*. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Galmed Holdings Inc.

We have audited the accompanying consolidated balance sheets of Galmed Holdings Inc. (a development stage company) (the Company) and its subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations and changes in shareholders' deficiency and cash flows for each of the two years in the period ended December 31, 2013 and for the period from September 11, 2000 (date of inception) to December 31, 2013. These consolidated financial statements are the responsibility of the Company's board of directors and management. Our responsibility is to express an opinion on these consolidated 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by the 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, such consolidated financial statements, present fairly, in all material respects, the financial position of the Company and its subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2013 and for the period from September 11, 2000 (date of inception) to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations and deficiency in stockholders' equity raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Brightman Almagor Zohar & Co.
Certified Public Accountants
A member firm of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel
February 4, 2014

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Galmed Holdings Inc.
(A development stage company)

Consolidated Balance Sheets
U.S. Dollars in thousands, except share data and per share data

		As of December 31,	
		2013	2012
Assets			
Current Assets			
Cash and cash equivalents		$ 137	$ 718
Other accounts receivable	3	16	14
Total current assets		153	732
Property and equipment, net	4	13	30
Total assets		$ 166	$ 762
Liabilities and Stockholders' Deficiency			
Current liabilities			
Short-term loan		$	$ 20
Trade payables		1,355	401
Other accounts payable	5	334	92
Total current liabilities		1,689	513
Long-term liabilities			
Convertible notes	6		1,824
Related parties	7	428	404
Total long-term liabilities		428	2,228

		Pro Forma As of December 31, 2013 Assuming the Reorganization Occurred(*) (unaudited)		
Stockholders' deficiency:				
Ordinary shares par value $1 per share; Authorized 50,000 shares; Issued and outstanding: 9,739 shares as of December 31, 2013 and 6,853 shares as of December 31, 2012	9	$ 20	10	7

Pro Forma-Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 7,099,731			
Additional paid-in capital	25,671	25,681	4,447
Capital note			3,724
Deficit accumulated during the development stage	(27,642)	(27,642)	(10,157)
Total stockholders' deficiency	$ (1,951)	(1,951)	(1,979)
Total liabilities and stockholders' deficiency		$166	$762

(*) See note 1.B.

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

Galmed Holdings Inc. (A development stage company) Consolidated Balance Sheets U.S. Dollars in thousands, ex 317

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Galmed Holdings Inc.
(A development stage company)

Consolidated Statements of Operations
U.S. Dollars in thousands, except share data and per share data

		Year ended December 31,		Period from September 11, 2000 (date of inception) to December 31, 2013
		2013	2012	
Research and development, expenses	10	$7,207	$2,443	$ 14,962
General and administrative expenses	11	7,355	694	9,675
Capital loss		10		10
Total operating expenses		14,572	3,137	24,647
Financial expenses, net	6	2,912	6	2,966
Loss before income taxes		17,484	3,143	27,613
Income taxes	12	1	6	29
Net loss		$17,485	$3,149	$ 27,642
Basic and diluted net loss per share from continuing operations		$2,514.38	$459.51	
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		6,954	6,853	
Pro Forma assuming the Reorganization occurred retroactively adjusted unaudited (*)				
Basic and diluted net loss per share from continuing operations		$3.45	$0.63	
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		5,069,466	4,995,837	

(*) See note 1.B.

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

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Galmed Holdings Inc.
(A development stage company)

Statements of Changes in Stockholders' Deficiency
U.S. Dollars in thousands, except share data and per share data

	Ordinary shares		Additional paid-in capital	Capital note	Deficit accumulated during the development stage	Total
	Shares	Amount				
Balance January 1, 2012	6,853	$7	$4,239	$52	$(7,008)	$(2,710)
Capital note				3,672		3,672
Stock based compensation expenses			208			208
Net loss					(3,149)	(3,149)
Balance December 31, 2012	6,853	7	4,447	3,724	(10,157)	(1,979)
Conversion of capital notes in December 2013	1,432	2	3,722	(3,724)		
Stock based compensation expenses			10,851			10,851
Conversion of loans in December 2013	1,408	1	6,541			6,542
Issuance of ordinary shares in December 2013	46	(*)	120			120
Net loss					(17,485)	(17,485)
Balance December 31, 2013	9,739	$10	$25,681	$	$(27,642)	$(1,951)

Cumulative from September 11, 2000 (date of inception) to December 31, 2013

	Ordinary shares		Additional paid-in capital	Capital note	Accumulated deficit	Total
	Shares	Amount				
Share issuance upon formation of the Company consideration for par value of shares	5,150	$5	$645	$	$	$650
Conversion of loans into ordinary shares in 2005	84	(*)	193			193
Conversion of loans into ordinary shares in 2007	92	(*)	212			212
	1,527	2	3,189			3,191

Conversion of loans into ordinary shares in 2008						
Stock based compensation expenses			11,059			11,059
Capital note in 2011				52		52
Capital note in 2012				3,672		3,672
Conversion of loans into ordinary shares in 2013	1,408	1	6,541			6,542
Conversion of capital notes in 2013	1,432	2	3,722	(3,724)		
Issuance of ordinary shares in 2013	46	(*)	120			120
Net loss for the period					(27,642)	(27,642)
Balance as of December 31, 2013	9,739	$10	$25,681	$	$(27,642)	$(1,951)

(*) Less than $1.

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

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Galmed Holdings Inc.
(A development stage company)

Consolidated Statements of Cash Flows
U.S. Dollars in thousands, except share data and per share data

	Year ended December 31,		Period from September 11, 2000 (date of inception) to December 31, 2013
	2013	2012	
Cash Flows from Operating Activities			
Net loss for the year	$(17,485)	$(3,149)	$(27,642)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4	5	21
Capital loss	10		10
Non-cash financial expenses due to convertible notes modification	2,878		2,878
Stock based compensation expense	10,851	208	11,059
Changes in operating assets and liabilities:			
increase in other accounts receivable	(2)	(11)	(16)
Increase (decrease) in trade payables	954	(89)	1,355
Increase (decrease) in other accounts payable	228	(103)	320
Increase in related party	38	60	442
Net cash used in operating activities	(2,524)	(3,079)	(11,573)
Cash Flows from Investing Activities			
Purchase of property and equipment	(13)	(32)	(60)
Proceed from sale of negotiable securities			85
Purchase of negotiable securities			(85)
Proceeds from Sale of property and equipment	16		16
Net cash provided by (used in) investing activities	3	(32)	(44)
Cash Flows from Financing Activities			
Credit from bank		(9)	
Receipt of short term loan from bank		26	26
Repayments of short term loan from bank	(20)	(6)	(26)
Receipt of convertible notes	1,840		7,260
Issuance of shares	120		770

Issuance of a capital note		3,672	3,724
Net cash provided by financing activities	1,940	3,683	11,754
Increase (decrease) in cash and cash equivalents	(581)	572	137
Cash and cash equivalents at the beginning of the year	718	146	
Cash and cash equivalents at the end of the year	$137	$718	$137
Non cash activity:			
Conversion of convertible loans into ordinary shares	$6,542	$	$10,138
Conversion of capital note into ordinary shares	$3,724	$	$3,724

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

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 1 General

A. General

Galmed Holdings Inc. (the Company) is a clinical stage biopharmaceutical company primarily focused on the development and commercialization of therapeutics for the treatment of liver diseases and cholesterol gallstones.

The Company was incorporated under the laws of the British Virgin Islands in 2000. Currently, the Company holds a wholly owned subsidiary, Galmed 2000 Inc., which was incorporated in the British Virgin Islands. Galmed 2000 Inc. holds a wholly owned subsidiary, Galmed International Limited, which was incorporated in Malta. Galmed International Limited holds a wholly owned subsidiary, Galmed Medical Research Ltd., which was incorporated in Israel.

Upon receiving a pre-ruling from the Israeli Tax Authorities, the Company intends to transfer all of its subsidiary shares and net assets to a new Israeli company, Galmed Pharmaceuticals Ltd. which upon such transfer will be owned by the same shareholders that own the Company in the same proportion as such shareholders currently own the Company. Galmed Pharmaceuticals Ltd. is then expected to offer its shares through an initial public offering in 2014.

On January 30, 2014, the pre-ruling from the Israeli Tax Authorities had been received.

B. Pro Forma Event

On February 2, 2014, the Company underwent a reorganization, pursuant to which all of its business, including its subsidiary's shares and net assets, was transferred to the Galmed Pharmaceuticals Ltd. (the Reorganization). For that purpose, Galmed Pharmaceuticals Ltd. was capitalized in a manner that was identical in share structure and holdings as the Company. Contemporaneously, Galmed Pharmaceuticals Ltd. effected a stock split of 729:1. The Reorganization is considered a restructuring under common control, pursuant to which Galmed Pharmaceuticals Ltd. is the successor and the Company is the predecessor. Because Galmed Pharmaceuticals Ltd. is considering consummating an IPO subsequent to the consummation of the Reorganization, the financial statements include the effect of the split in a pro forma stockholders presentation and retroactively reflected the effect of the stock split in a pro forma earnings per share presentation.

C. Going concern

As reflected in the accompanying financial statements, the Company s operations for the year ended December 31, 2013, resulted in a net loss of $17,485. The Company s balance sheet reflects an accumulated deficit of $27,642. These conditions, together with the fact that the Company is a development stage company and has no revenues nor are revenues expected in the near future, raise substantial doubt about the Company's ability to continue to operate as a

going concern . The Company s ability to continue operating as a going concern is dependent on several factors, among them is its ability to raise sufficient additional working capital.

These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 2 Significant accounting policies

A. Basis of presentation:

The consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles (U.S. GAAP) applied on a consistent basis.

B. Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

C. Financial statement in U.S. dollars:

The functional currency of the Company and its subsidiaries is the U.S. dollar (dollar) because the dollar is the currency of the primary economic environment in which the Company and its subsidiaries has operated and expects to continue to operate in the foreseeable future.

Transactions and balances denominated in dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to dollars in accordance with the provisions of ASC 830-10, Foreign Currency Translation . All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

D. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Galmed 2000 Inc., Galmed International Limited and Galmed Medical Research Ltd. All intercompany balances and transactions have been eliminated upon consolidation.

E. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with maturities of three months or less as of the date acquired.

F. Property and equipment:

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets.

The annual depreciation rates are as follows:

	%
Vehicles	15
Office furniture and equipment	7
Computer software and electronic equipment	33

G. Impairment of long-lived assets:

The Company s and its subsidiaries long-lived assets are reviewed for impairment in accordance with ASC 360-10, Accounting for the Impairment or Disposal of Long-Lived Assets, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 2 Significant accounting policies (continued)

the amount by which the carrying amount of the assets exceeds their fair value. During 2013 and 2012, no impairment losses were identified.

H. Severance pay:

The Company's liability for severance pay is calculated in accordance with Israeli law based on the most recent salary paid to each employee and the length of employment with the Company. Part of the liability is funded through individual insurance policies purchased from outside insurance companies, which are not under the Company's control. Some of the employees of the Company are included under section 14 of the Severance Compensation Act, 1963 (section 14) for a portion of their salaries. According to section 14, these employees are entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with such insurance companies.

Payments in accordance with section 14 release the Company from any future severance payments (under the Severance Compensation Act, 1963) with respect of those employees. The aforementioned deposits are not recorded as an asset in the Company's balance sheet.

I. Fair value of financial instruments

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

The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments:

The carrying amounts of cash and cash equivalents, short-term bank deposits and trade payables approximate their fair value due to the short-term maturity of such instruments.

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

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets;

Level 2	Other inputs that are directly or indirectly observable in the marketplace; and
Level 3	Unobservable inputs which are supported by little or no market activity.

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.

J. Convertible note

The Company examines its issued convertible notes first under ASC 470-20 Debt with Conversion and Other Options , according to which the proceeds from the sale of debt securities with a conversion feature and or other options are allocated to each of the securities issued based on their relative fair value.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 2 Significant accounting policies (continued)

The Company also examined its issued convertible notes under ASC Topic 815 Derivatives and Hedging , that generally provides criteria that, if met, require companies to bifurcate conversion options from their host instruments and account for them as freestanding derivative financial instruments. These three criteria are (i) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument subject to the requirements of ASC Topic 815. In determining whether the embedded derivative should be bifurcated, the Company considers all other scope exceptions provided by that topic. One scope exception particularly relevant to convertible instruments is whether the embedded conversion feature is both indexed to and classified in the Company's equity.

The Company further considered whether, under ASC 470-20-25, a beneficial conversion feature exists. If so, then the Company should have allocated the beneficial conversion feature to an equity component based on the benefit of the conversion terms granted to purchasers on the issuance date.

The Company examined and determined that no beneficial conversion feature exists under ASC 470-20. The Company also examined and determined that no derivative financial instrument exists that is subject to the requirements of ASC Topic 815 that should be bifurcated and separately accounted for as a derivative financial instrument.

K. Accounting for stock-based compensation:

The Company applies ASC 718-10, Share-Based Payment, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options under the Company's stock plans based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of operations.

The Company recognizes compensation expense for the value of non-employee awards, which have graded vesting, based on the accelerated attribution method over the requisite service period of each award, net of estimated forfeitures.

The Company recognizes compensation expense for the value of employee awards, which have graded vesting, based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures.

The Company estimates the fair value of restricted shares based on the market price of the shares at the grant date and estimates the fair value of stock options granted using a Black-Scholes option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility was calculated based upon actual historical stock price movements over the period, which is equal to the expected option term. The expected option term was calculated for options granted to employees and directors in accordance with ASC-718-10-S99, using the simplified method. Grants to non-employees are based on the contractual term. The Company has historically not paid dividends and has no

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 2 Significant accounting policies (continued)

foreseeable plans to pay dividends. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term.

The following assumptions were used for the fiscal year 2013 and 2012 grants: dividend yield of 0.00% for both periods; risk-free interest rate between 0.91% and 1.71%; an expected life between three and five years; and a volatility rate between 67% and 70%.

L. Research and development expenses:

Research and development expenses are charged to the statement of operations as incurred.

M. Income taxes:

The Company accounts for income taxes utilizing the asset and liability method in accordance with ASC 740, Income Taxes . Current tax liabilities are recognized for the estimated taxes payable on tax returns for the current year. Deferred tax liabilities or assets are recognized for the estimated future tax effects attributable to temporary differences between the income tax bases of assets and liabilities and their reported amounts in the financial statements and for tax loss carry forwards. Measurement of current and deferred tax liabilities and assets is based on provisions of enacted tax laws and deferred tax assets are reduced, if necessary, by the amount of tax benefits, the realization of which is not considered more likely than not based on available evidence.

ASC 740-10 requires a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement.

N. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of shares outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares outstanding during each year, plus the dilutive potential of the ordinary shares considered outstanding during the year, in accordance with ASC 260-10, Earnings per Share .

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2013 and 2012 because all such securities have an anti-dilutive effect.

Note 3 Other accounts receivable

	As of December 31	
	2013	2012
Government institutions	$ 11	$ 10
Prepaid expenses	5	4
	$ 16	$ 14

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 4 Fixed assets, net

	As at December 31	
	2013	2012
Vehicles	$	$ 29
Office furniture and equipment	3	2
Computer software and electronic equipment	27	16
	30	47
Accumulated depreciation	17	17
Net book value	$ 13	$ 30

Note 5 Other accounts payable

	As of December 31	
	2013	2012
Accrued expenses	$ 236	$ 24
Related party		10
Employees and related institutions	22	
Accrued vacation(*)	76	58
	$ 334	$ 92

(*) Including inter alia due to a related party in the amount of $70 and $56, as of December 31, 2013 and 2012, respectively.

Note 6 Convertible notes

A. From August through October 2013, the Company issued short-term convertible notes to various investors (the Investors) in the aggregated amount of $1,840. Such notes were convertible into ordinary shares of the Company based on a price per share of $5,433. On December 1, 2013, the Company and the Investors signed an amendment that lowered the conversion price per share to $2,601. The discussion with the Investors was in contemplation of the Company raising capital by issuing ordinary shares as described in Note 9.A.5 in which the Company agreed to issue shares at a discounted per share price due to liquidity requirements. The Company agreed to the modification of the convertible notes to the discounted per share price determined in the negotiations with the ordinary share investors.

The Company applied the provisions of ASC 470-50 Modifications and Extinguishments to account for debt modification. The Company first determined that the exchange was not considered a troubled debt restructuring, mainly due to the fact that no concession was granted by the creditor. Based on the provisions of ASC 470-50, the Company determined that the exchange resulted in an extinguishment of the old convertible notes and the issuance of new convertible notes.

The Company recorded the new convertible notes at their fair value. The difference between the fair value of the new convertible notes and the net carrying amount of the extinguished notes, in the amount of approximately $2,878, was recorded in the statement of operations report as a financial expense for the year ended December 31, 2013.

The Company determined the fair value of the new convertible notes using the present value techniques that are commensurate with valuation techniques used in valuation of convertible notes, which considers the fair value of the loan and the fair value of the conversion feature.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 6 Convertible notes (continued)

The following significant assumptions were used for measuring the fair value of the new convertible notes: dividend yield of 0.00%; risk-free interest rate of 1.71%; an expected life of 5 years; a volatility rate of 70%; and a discount rate of 20%.

On December 10, 2013, upon the convertible notes holders' request, the notes fully converted into 707 ordinary shares, $1 par value.

B. In December 2013, upon the convertible notes holders request, the Company converted all of its remaining outstanding convertible notes into 1,408 ordinary shares, $1 par value.

Note 7 Related parties

A. Balances:

1. On January 1, 2007, the Company entered into a consulting agreement with a consulting company (the Consulting Company) owned by a member of the Company's Board of Directors, who is also the Company's current CEO and a shareholder of the Company. The maximum monthly consideration for the services provided pursuant to the agreement is $10.
   In 2011, the Company entered into an agreement with the Consulting Company whereby the Consulting Company agreed to waive most of the consulting fees under its agreement.

As of December 31, 2012, the Company had an accrual in the amount of $10 to the Consulting Company due to prior years fees.

In January 2012, the Consulting Company increased the scope of its services and, accordingly, the monthly fee was increased to $20. Later in 2012, the Consulting Company agreed to waive the majority of its 2012 fees

As of December 31, 2013, the Company had no debt relating to the agreement with the Consulting Company mentioned above.

2. As of December 31, 2013 and 2012, the Company had an accrual in the amount of $223 and $189, respectively, pursuant to an employment agreement with its CEO, who is also a shareholder of the Company.
3. As of December 31, 2012, the aggregate outstanding amount of convertible notes held by shareholders was $574.
4. In December 2011, the Company signed an agreement with the beneficiaries of one of its co-founders which states that the beneficiaries are entitled to an aggregate amount of $263 as a result of outstanding obligations of the

Company owed to the late co-founder. Such amount is subject to annual interest equal to LIBOR + 1.

As of December 31, 2013 and 2012, the aggregate outstanding amount of the aforementioned liabilities was $275 and $270, respectively.

B. Transactions:

1. During 2013 and 2012, the Company recognized consulting fees and expenses owed to the Consulting Company in the amount of $10 and $20, respectively.
2. During 2013 and 2012, the Company recorded salary expenses in the amount of $34 and $55, respectively, as a result of an employment agreement with its CEO, who is also a shareholder of the Company.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 7 Related parties (continued)

3. In 2012, the Company issued 331 options to purchase ordinary shares of the Company to the chairman of its Board of Directors. During 2013 and 2012, the stock-based compensation expenses with respect to the options amounted to $101, and $208 respectively. See also Note 9.

4. During 2012, the Company issued 331 warrants to purchase ordinary shares of the Company to an investor. The vesting period of the warrants is based on performance milestones. During 2013 and 2012, the expenses recorded with respect to the warrants amounted to $0. See also Note 9.

5. During the year 2013 and during the years 2009 through 2011, the Company issued convertible notes in the amount of $1,215 and $574, respectively, to various existing shareholders. See Note 6 above. In December 2013, upon the convertible notes holders' request, the notes were fully converted.

6. In December 2013, the Company granted 1,106 options to purchase ordinary shares of the Company, $1 par value, to certain directors. The options will vest over various periods not exceeding two years and will expire in September 2023. The exercise price is between $0.01 and $2,601 per share. As of December 31, 2013, 986 of such options were vested. The aggregate grant date fair value of such options is $7,789. During the year 2013, the Company recorded stock based compensation expenses in the amount of $6,960, with respect to the above mentioned options.

Note 8 Commitments and contingencies

1. In 2002, the Company entered an agreement with Aventis Pharma Deutschland GmbH. (Aventis), in which Aventis agreed that the Company will have the exclusive worldwide right to commercialize an invention covered by Israeli patent application 123998 and PCT/IL99/00173, and the Company agreed to pay Aventis a royalty of 10% in respect of all income that the Company or its affiliates may receive from the commercialization of such invention which is related to the prevention and treatment of gallstones.

Note 9 Shareholders' deficiency

A. Ordinary shares:

1. Ordinary shares confer upon the holders the right to receive notice to participate and vote in general meetings of the Company and the right to receive dividends, if declared.
2. During the period from September 11, 2000 (date of inception) through 2009, 6,853 ordinary shares were issued in consideration of $4,246.
3. In December 2013, upon the convertible notes holders request, the Company converted all of its outstanding convertible notes into 1,408 ordinary shares $1 par value.
4. In December 2013, upon the capital notes holders request, the Company converted all of its capital notes into 1,432 ordinary shares $1 par value. See Note B below.

5. On December 31, 2013, the Company signed an agreement with an investor in which the Company issued to the investor 46 ordinary shares, $1 par value, in consideration of $120.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 9 Shareholders' deficiency (continued)

B. Capital notes:

During the years 2012 and 2011, the Company signed agreements with various investors, according to which the Company issued to investors capital notes in the aggregate amount of $3,724.

The capital notes are instruments of equity and not debt. The capital notes holders may convert the face amount of the capital notes, in whole or in part, without additional consideration, into ordinary shares of the Company, however, prior to such conversion, if at all, the capital notes (i) do not grant their holders with any of the rights of the Company's shareholders; (ii) have no maturity date, do not carry interest, are not linked to any index and are not redeemable; and (iii) are not registered.

Accordingly the Company classified such capital notes as an equity component.

In 2013, the capital notes were fully converted into 1,432 ordinary shares.

C. Stock-based compensation:

1. During 2002, the Company granted 53 options to purchase ordinary shares of the Company to a service supplier (the service supplier). The options were fully vested at the grant date, as set forth in the agreement signed by the parties. The exercise price is $1,075 per option. As of December 31, 2013, all the aforementioned options were outstanding.

2. During 2012, the Company granted 331 options to purchase ordinary shares of the Company, $1 par value to its chairman of the Board of Directors. The options will vest over a period of three years and will expire four years from the vesting date. In the event of an IPO, such options will become fully vested. These options will expire in the event of an IPO unless exercised. The exercise price is $2,601 per option. As of December 31, 2013, 220 of such options were vested.

3. In December 2013, the Company granted 1,673 options to purchase ordinary shares of the Company, $1 par value to certain consultants and directors. 1,553 of those options vested immediately, and the remaining 120 options will vest over two years. The options will expire in September 2023. The exercise price is between $0.01 and $2,601 per share. As of December 31, 2013, 1,553 of such options were vested.

4. A summary of the status of the Company's option plans as of December 31, 2013 and 2012 and changes during the years then ended are presented below:

	December 31, 2013	2012

	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price
Options outstanding at beginning of year	384	$ 2,390	53	$ 1,075
Granted	1,673	$ 463	331	$ 2,601
Outstanding at end of year	2,057	$ 823	384	$ 2,390
Options exercisable at year-end	1,826	$ 743	163	$ 2,105

As of December 31, 2013, the weighted-average remaining contractual term of the outstanding and exercisable options, excluding the 53 options granted in 2002 which have no expiration date, is 8.74 and 8.91 years, respectively.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 9 Shareholders' deficiency (continued)

As of December 31, 2013, all of the outstanding and exercisable options are in-the-money with aggregate intrinsic values of $13,209 and $11,871, respectively.

The unrecognized compensation expense calculated under the fair value method for stock options expected to vest as of December 31, 2013 is approximately $456 and is expected to be recognized over a weighted-average period of 2 years.

The weighted average grant date fair value of the options granted in 2013 was $6,921.

D. Warrants:

During 2012, the Company granted 311 warrants to purchase ordinary shares of the Company to an investor (the Investor), who was to assist the Company in establishing business connections and opportunities, negotiating with third parties and fundraising. The warrants vest upon the occurrence of several performance-based conditions, as set forth in the agreement signed by the parties. The exercise price is $2,601. As of December 31, 2013, the calculated fair value of the warrants was $274. The Company estimates the fair value of the warrants using the Black-Scholes option pricing model. The following assumptions were used for the Black-Scholes option pricing model: dividend yield of 0.00%; risk-free interest rate of 0.28%; an expected life of 1.5 years; and a volatility rate of 67%.

The Company estimated that the performance-based conditions set forth in the agreement would not be met and accordingly did not record expenses due to the warrants. The warrants expired in May 2013.

Note 10 Research and development, costs

	Year ended December 31		Period from September 11, 2000 (date of inception) to December 31, 2013
	2013	2012	
Chemistry and formulation studies	$ 2,081	$ 1,759	$ 7,366
Stock based compensation	4,285		4,285
Research and pre-clinical studies	711	409	1,930

Clinical studies	128	171	1,274
Business development	2	104	107
	$ 7,207	$ 2,443	$ 14,962

Note 11 General and administrative expenses

	Year ended December 31		Period from September 11, 2000 (date of inception) to December 31, 2013
	2013	2012	
Stock based compensation	$ 6,566	$ 208	$ 6,774
Professional fees	496	114	888
Salaries and benefits	145	184	871
Traveling and conference costs	46	83	334
Rent and office maintenance fees	46	38	125
Others	56	67	683
	$ 7,355	$ 694	$ 9,675

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 12 Taxes on income

A. General

The Company is assessed for tax purposes on an unconsolidated basis. Each of the Company s subsidiaries is subject to the tax rules prevailing in its country of incorporation.

B. Corporate Taxation

1. Israeli subsidiary:

a. Taxable income of Israeli companies is subject to tax at the rate of 25% in 2012 and 2013 (Regular Tax Rate).

b. On July 30, 2013, the Knesset Plenum approved, in a third reading, the budget bill and the bill to change the national priorities in 2013 and 2014 (the Law). In conjunction with this legislation there will be an increase of the corporate income tax rate from January 1, 2014 to 26.5% (1.5% increase).

2. Maltese subsidiary:

Taxable income of Maltese companies is subject to tax at the rate of 35% in 2012 and 2013 (Regular Tax Rate).

C. Net operating loss carry forwards

As of December 31, 2013, Galmed International Limited had approximately $15,759 of Maltese net operating loss carry forwards. The Maltese loss carry forwards have no expiration date.

D. Deferred income taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company s and its subsidiaries assets are as follows:

	As of December 31,	
	2013	2012
Deferred tax assets:		
Maltese subsidiary net operating loss carry forward	$ 5,516	$ 3,789
Other reserves and allowances	115	122
Total deferred tax assets	5,631	3,911
Valuation allowance	(5,631)	(3,911)
Net deferred tax assets	$	$

Deferred tax assets for carry forward losses in Malta are calculated using the applicable tax rate at the time of expected realization of the carry forward losses.

The Company has provided full valuation allowances in respect of deferred tax assets. Management currently believes that it is more likely than not that those deferred taxes will not be realized in the foreseeable future.

E. Tax assessments

The Israeli subsidiary has received final tax assessments through the year ended December 31, 2010.

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Galmed Holdings Inc.
(A development stage company)

Notes to Consolidated Financial Statements
U.S. Dollars in thousands, except share data and per share data

Note 12 Taxes on income (continued)

F. A reconciliation of the Company's effective tax expense to the Company's theoretical statutory tax benefit is as follows:

	Year ended December 31,	
	2013	2012
Loss before taxes on income, as reported in the consolidated statements of operations	$17,484	$3,143
Statutory tax rate	25 %	25 %
Theoretical tax benefit	4,371	786
Losses and other items for which a valuation allowance was provided or benefit from loss carry forwards	(4,371)	(786)
Other	1	6
Actual tax expense	$1	$6

Note 13 Subsequent event

See note 1.A.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of Galmed Pharmaceuticals Ltd.

We have audited the accompanying balance sheet of Galmed Pharmaceuticals Ltd. (the Company) as of December 31, 2013. This financial statement is the responsibility of the Company s management. Our responsibility is to express an opinion on this financial statement based on our audit.

We conducted our audit 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 statement is free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such balance sheet presents fairly, in all material respects, the financial position of the Company as of December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

Brightman Almagor Zohar & Co.
Certified Public Accountants
A member firm of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel
February 4, 2014

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GALMED PHARMACEUTICALS LTD.

BALANCE SHEET
December 31, 2013

ASSETS	
Cash and cash equivalents	$
Total assets	$
LIABILITIES AND STOCKHOLDERS EQUITY	
Commitments and contingencies	
Stockholders equity	
Ordinary shares, NIS 0.01 par value; 50,000,000 shares authorized; 7,099,731 share issued and outstanding	$
Total liabilities and stockholders equity	$

See accompanying Notes to Financial Statement

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GALMED PHARMACEUTICALS LTD.

NOTES TO FINANCIAL STATEMENT

Note 1 Organization and Nature of Business Operations

Galmed Pharmaceuticals Ltd. (the Company), an Israeli Company, was formed on July 31, 2013 and has not started its activity. Upon receiving a pre-ruling (the Pre-ruling) from the Israeli Tax Authorities, Galmed Holdings Inc. (owned by the same shareholders that own the Company in the same holding percentage) intends to transfer all of its subsidiary shares and net assets to the Company. The Company is then expected to offer its shares through an initial public offering in 2014.

On January 30, 2014 the pre-ruling from the Israeli Tax Authorities had been received.

On February 2, 2014, the Company underwent a reorganization (the Reorganization), pursuant to which all of Galmed Holdings Inc.'s business, including its subsidiary's shares and net assets, was transferred to the Company. The Reorganization is considered a restructuring under common control with the Company as the successor and Galmed Holdings Inc. as the predecessor.

Note 2 Summary of Significant Accounting Policies

The accompanying financial statement is presented in conformity with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the Securities and Exchange Commission, and, in the opinion of management, include all adjustments necessary for a fair presentation of the financial position as of the date presented.

Note 3 Shareholders Equity

At the date of incorporation, the Company is authorized to issue 50,000,000 shares of ordinary shares, par value NIS 0.01. As of December 31, 2013, 7,099,731 shares are issued and outstanding.

On December 30, 2013, as part of the Reorganization and as required by the Pre-ruling, the Company issued and allotted 7,099,731 ordinary shares to the shareholders of Galmed Holdings Inc. for no consideration, such that their respective holdings in the Company are identical to their holdings in Galmed Holdings Inc. (on a 729:1 ratio basis).

On December 30, 2013, as part of the Reorganization and as required by the Pre-ruling, the Company granted 1,499,553 options to purchase ordinary shares of the Company, par value NIS 0.01, to certain consultants and directors, such that their respective holdings in the Company on a fully diluted basis are identical to their holdings in Galmed Holdings Inc. on a fully diluted basis. The options will vest over various periods not exceeding two years and will expire in September 2023. The exercise price is between $0.01 and $3.57 per share. As of December 31, 2013, 1,331,154 of such options were vested.

Note 4 Income Taxes

Prior to the completion of the Reorganization, the Company did not have any taxable income. The Company is subject to statutory tax requirements of the locations in which it conducts its business.

Note 5 Subsequent Event

A. On February 3, 2014 the Company entered into a share purchase agreement with certain of its shareholders and new investors, pursuant to which the Company issued to such existing shareholders and new investors 560,224 ordinary shares at a price per share of $3.57 for a total consideration of $2.0 million.

B. See also note 1.

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2,837,400 ORDINARY SHARES

GALMED PHARMACEUTICALS LTD.

PROSPECTUS

Sole Book-Running Manager

Maxim Group LLC

Co-Managers

MLV & Co. **Feltl and Company**

Prospectus dated March 12, 2014.

Until and including April 6, 2014, 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.