Galmed Pharmaceuticals Ltd.
Form F-3
March 31, 2015

As filed with the Securities and Exchange Commission on March 31, 2015

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM F-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

State of Israel	**Not Applicable**
(*State or other jurisdiction of incorporation or organization*)	(*I.R.S. Employer Identification No.*)

Galmed Pharmaceuticals Ltd.

8 Shaul Hamelech Blvd.

Amot Mishpat Bldg.

Tel Aviv, Israel 64733

Tel: 972.3.6938.448

(Address and telephone number of Registrant's principal executive offices)

Allen Baharaff, President and Chief Executive Officer

Galmed Pharmaceuticals Ltd.

8 Shaul Hamelech Blvd.

Amot Mishpat Bldg.

Tel Aviv, Israel 64733

Tel: 972.3.6938.448

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Andrew P. Gilbert, Esq.

DLA Piper LLP (US)

51 John F. Kennedy Parkway, Suite 120

Short Hills, New Jersey 07078

(973) 520-2550

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Amount to be registered[1]**	**Proposed maximum aggregate price per share[1]**	Proposed maximum aggregate offering price	Amount of registration fee
Ordinary shares, par value NIS 0.01 per share	(2)	(2)	$ 150,000,000	$ 17,430 (3)

(1) There are being registered under this registration statement such indeterminate number of ordinary shares, as may be sold by the registrant from time to time, which collectively shall have an aggregate initial offering price not to exceed $150,000,000. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended, or the Securities Act, the ordinary shares being registered hereunder include such indeterminate number of ordinary shares as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(2) Omitted pursuant to Rule 457(o) under the Securities Act.

(3) The registration fee has been calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, on the basis of the maximum aggregate offering price of the securities listed.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed or supplemented. No securities described in this prospectus can be sold until the registration statement that we filed to cover the securities has become effective under the rules of the Securities and Exchange Commission. This prospectus is not an offer to sell the securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED March 31, 2015

PROSPECTUS

GALMED PHARMACEUTICALS LTD.

$150,000,000

Ordinary Shares

The Company may offer and sell from time to time in one or more offerings our ordinary shares having an aggregate offering price up to $150,000,000.

Each time we sell ordinary shares pursuant to this prospectus, we will provide in a supplement to this prospectus the price and any other material terms of any such offering. Any prospectus supplement may also add, update or change information contained in the prospectus. You should read this prospectus and any applicable prospectus supplement, as well as the documents incorporated by reference or deemed incorporated by reference into this prospectus, carefully before you invest in any securities. **This prospectus may not be used to offer or sell securities unless accompanied by a prospectus supplement**.

Our ordinary shares are traded on the NASDAQ Capital Market under the symbol “GLMD.” The closing price of our ordinary shares, as reported on the NASDAQ Capital Market on March 26, 2015, was $10.31.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds, before expenses, to Galmed Pharmaceuticals Ltd.	$	$

For additional information on the methods of sale, you should refer to the section titled “Plan of Distribution.” If any underwriters are involved in the sale of our securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

INVESTING IN OUR ORDINARY SHARES INVOLVES A HIGH DEGREE OF RISK. SEE “RISK FACTORS” BEGINNING ON PAGE 8 OF THIS PROSPECTUS TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE PURCHASING OUR ORDINARY SHARES.

Neither the Securities and Exchange Commission, nor the Israel Securities Authority or any state securities commission has approved or disapproved of these securities or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense under the laws of the United States and the laws of the State of Israel.

The date of this prospectus is 2015

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About this Prospectus

This prospectus is part of a Registration Statement on Form F-3 that we filed with the Securities and Exchange Commission, or the SEC, utilizing a "shelf" registration process. Under this shelf process, we may sell the ordinary shares described in this prospectus in one or more offerings. We sometimes refer to our ordinary shares as the "securities" throughout the prospectus. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Accordingly, you should refer to the registration statement and its exhibits for further information about us and our ordinary shares. Copies of the registration statement and its exhibits are on file with the SEC. Statements contained in this prospectus concerning the documents we have filed with the SEC are not intended to be comprehensive, and in each instance we refer you to a copy of the actual document filed as an exhibit to the registration statement or otherwise filed with the SEC.

Each time we sell ordinary shares, we will provide you with a prospectus supplement that will describe the specific amounts, prices and terms of such offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under "Where You Can Find More Information and Incorporation by Reference."

This prospectus does not contain all of the information provided in the registration statement that we filed with the Commission. For further information about us or our ordinary shares, you should refer to that registration statement, which you can obtain from the Commission as described below under "Where You Can Find More Information and Incorporation by Reference."

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. "Incorporated by reference" means that we can disclose important information to you by referring you to another document filed separately with the SEC. We have not authorized anyone to provide you with different information. We are offering to sell, and seeking offers to buy, our ordinary shares only in jurisdictions where offers and sales are permitted. We are not making, nor will we make, an offer to sell securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and any supplement to this prospectus is current only as of the dates on their respective covers. Our business, financial condition, results of operations and prospects may have changed since that date.

We may sell our ordinary shares to underwriters who will sell the securities to the public at a fixed offering price or at varying prices determined at the time of sale. The applicable prospectus supplement will contain the names of the underwriters, dealers or agents, if any, together with the terms of offering, the compensation of those underwriters, dealers or agents and, in the case of a sale by us, the net proceeds to us. Any underwriters, dealers or agents participating in the offering may be deemed "underwriters" within the meaning of the Securities Act of 1933, as

amended, or the Securities Act.

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

Unless the context in which such terms are used would require a different meaning, all references to “Galmed,” “us,” “we,” “our,” the “Company” or “the registrant” refer to Galmed Pharmaceuticals Ltd. and its consolidated subsidiaries. All references to “$,” “dollar” or “U.S. dollar” are to the legal currency of the United States of America, references to “NIS” or “New Israeli Shekel” are to the legal currency of Israel and references to “Euro” are to the legal currency of the European Union.

About Galmed Pharmaceuticals Ltd.

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, referred to herein as the Group. Originally, we operated under the parent company, Galmed Holdings Inc., a holdings company incorporated in the British Virgin Islands, or GHI. GHI held all of the equity rights in and to Galmed 2000 Inc., a holdings company incorporated in the British Virgin Islands, or GTTI. GTTI held all of the equity rights in and to Galmed International Limited, or GIL, a company incorporated in Malta, a European Union, or EU, member state (other than one share held by Galmed Research and Development Ltd., a newly formed Israeli company, or GRD)). GIL held all of the equity rights in and to Galmed Medical Research Ltd., an Israeli company referred to herein as GMR. 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 the Reorganization, pursuant to which all of our current 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 the entire share capital of GTTI to the Company; next, GTTI transferred the entire share capital of GIL to the Company; then, GIL transferred and assigned all of its intellectual property to GRD. GIL held all of the equity rights in and to GMR. 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) GRD, 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 an inactive company that we expect to liquidate at or following the end of 2015. GIL holds GMR, which became an inactive company in 2014. The Reorganization was conducted in order to simplify our capital structure, reduce our operating cost and to improve our ability to raise funds. 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 (as described in the Company’s Form 20-F filed with the SEC on March 31, 2015), 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 our initial public offering, as more fully described in our Annual Report on Form 20-F for the year ended December 31, 2014, as filed with the SEC on March 31, 2015. Among other things, the Tax Pre-Ruling required that as of immediately prior to the completion of the Reorganization, the shareholders, option holders and other rights holders of GHI and the Company had to be identical, and that their respective holdings in each of GHI and the Company also had to be identical.

The following is a diagram of our corporate structure following the liquidation of GTTI:

During May 2014, we completed our initial public offering in the United States. In connection with our initial public offering, we listed our ordinary shares on the Nasdaq Capital Market and issued 3,363,010 of our ordinary shares in consideration of approximately $39.7 million, after deducting underwriting discounts, commissions and other estimated offering expenses.

Our principal executive offices and registered office in Israel are located at 8 Shaul Hamelech Blvd., Amot Mishpat Bldg., Tel Aviv, Israel, 6473307 and our telephone number is +972 3-6938448. Our website address is http://www.galmedpharma.com. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into this report. We have included our website address solely as an inactive textual reference. Puglisi & Associates serves as our authorized representative in the United States. Its address is 850 Library Avenue, Newark, Delaware 19711.

Other than as described in “Item 5. Operating and Financial Review and Prospects—Contractual Obligations” of our Annual Report on Form 20-F for the year ended December 31, 2014, as filed with the SEC on March 31, 2015, we currently do not have and did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, as of December 31, 2014.

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 (referred to herein as FABAC) called aramchol. We believe that aramchol has the potential to be a disease modifying treatment for fatty liver disorders, including 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 (referred to herein as 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. There is currently no approved drug for the treatment of NASH. According to a joint workshop held on September 5 - 6, 2013, sponsored by the U.S. Food and Drug Administration (referred to herein as the FDA) and the American Association For The Study of Liver Diseases (referred to herein as AASLD) to develop guidance on diagnostic and therapeutic modalities for NASH, the FDA is currently working on guidelines for the development of therapies for the treatment of NASH. A recently published manuscript that summarizes the discussion at this joint workshop entitled "CHALLENGES AND OPPORTUNITIES IN DRUG AND BIOMARKER DEVELOPMENT FOR NONALCOHOLIC TEATOHEPATITIS: FINDINGS AND RECOMMENDATIONS FROM AN AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES (AASLD) - FOOD AND DRUG ADMINISTRATION (FDA) JOINT WORKSHOP" clarified, among other things, that the reversal of steatohepatitis with no evidence of progression to advanced fibrosis (stage 3 or 4), may be an acceptable surrogate endpoint suitable both for Phase IIb and Phase III trials that enroll patients with NASH and evidence of early fibrosis.

According to an article in 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 an article in 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 an article in the Journal of Hepatology in 2008, and as summarized in an article 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 an article in the Journal of Gastroenterology in 2005, NASH increases overall mortality by between 35% and 85%. NASH patients are also twice as likely to die from cardiovascular disease as the global general population. Publications over the last five years that addressed the connection between NASH and its cardiovascular complications include data from 18 studies with a total of 263,000 patients, with a follow up between 4.6 - 24 years. These studies reveal that the presence of NASH and NAFLD increases the risk of cardiovascular events by between 50% in females and up to 600% in males. An article in the European Scientific Journal in 2013 indicates that the

presence of NASH increases the cardiovascular risk by a multiple of 2.4 in addition to the other metabolic risk factors, such as type 2 diabetes, and stresses the importance of treating NASH to prevent cardiovascular disease in addition to the known hepatic complications.

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 suggest 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 prevent the hepatic and cardiovascular complications associated therewith.

On February 1, 2015, we began our ARREST Study, a multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase IIb clinical trial of aramchol, which we intend to conduct in 240 biopsy-diagnosed NASH patients who also suffer from obesity and insulin resistance. We have initially initiated this study in Israel, and depending on the timing of the respective National Regulatory Authorities' approval, we may also initiate the study in Europe and Latin America. Furthermore, we have also submitted to the FDA an update of our existing IND filing, including the results of chronic toxicology and human pharmacokinetic (referred to herein as PK) studies, in order to initiate the study in the United States. Our ARREST Study for aramchol in NASH patients is in accordance with the study design recommended by the Medicines and Healthcare Products Regulatory Agency, or MHRA, and has been deemed acceptable by Bundesinstitut für Arzneimittel und Medizinprodukte, a German medical agency, or BfArM, a German medical agency, and deemed satisfactory by Agence nationale de sécurité du médicament, a French medical agency, or ANSM. The study design has 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 ARREST 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 complete results from our ARREST Study to be available at the end of 2016. Once 120 patients in our ARREST Study complete six months of treatment, we intend to conduct an interim analysis for safety and futility of aramchol based on magnetic resonance spectroscopy, or MRS, analysis. The interim analysis will provide safety data according to which an independent safety board will decide whether to continue studying both doses or move all patients to one dose, if one is found to be safer than the other. The MRS will provide data for a futility decision, namely the decision to stop the study if no trend of reduction in liver fat content is found. We do not anticipate the interim results to lead to the stoppage of the ARREST Study, but no assurance can be given. This highlights the importance of the main secondary endpoint of the resolution of NASH in biopsies, which can be assessed only at the completion of the study and by repeated liver biopsies. We currently expect results from the interim analysis to be available in the first half of 2016**.** Depending on a number of factors, including, but not limited to, having sufficient resources and the completion of a pre-clinical study in juvenile animals, we may conduct in the future, but give no assurance that we will conduct or when we will conduct, an open-label Phase I clinical trial of aramchol in children**.**

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We are also exploring other indications for the use of aramchol, including the treatment of cholesterol gallstones. On November 13, 2014, we announced the first administration of aramchol in a proof-of-concept Phase IIa clinical trial for the treatment of newly formed cholesterol gallstones following bariatric surgery. The Phase IIa trial is a multi-center, randomized, double blind, placebo controlled study, designed to evaluate the efficacy and safety of a once-daily dose of aramchol for three months in 36 adult patients and is being conducted in four medical centers in Israel. The primary endpoint of the trial is the complete dissolution of newly formed cholesterol gallstones following bariatric surgery. Secondary endpoints include a decrease of more than 50% in the number of newly formed gallstones, prevention of the formation of additional gallstones during the trial period and dissolution of biliary sludge. We currently anticipate reporting top line results in the second half of 2015. Approximately 5% of the general population in most countries develops cholesterol gallstones and the current standard of care is surgery, either laparoscopic or open cholecystectomy.

On April 28, 2014, we commenced PK and food effect studies of aramchol. In written correspondence from December 2013 regarding a requested pre- IND application meeting, the FDA recommended that we conduct such studies prior to commencing our Phase IIb ARREST Study of aramchol for the treatment of NASH. We conducted the PK study at the Sourasky Medical Center in Tel Aviv, Israel. We enrolled 66 healthy male volunteers who received three doses of aramchol: 200mg, 400mg and 600mg. The two higher doses will be used in our ARREST Study. In December 2014, we completed the statistical analysis of the PK study of the three doses of aramchol and observed no serious adverse events. Such PK study provides additional safety data to further support existing safety data from our pre-clinical studies and our Phase I and Phase IIa clinical trials of aramchol.

To date, we have successfully completed four 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 serious adverse side effects were observed. 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, suggested 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 induced positive trends of changes in several metabolic parameters. The fourth was a single-site, randomized, partially double-blind, placebo-controlled PK and food effect study conducted in three parts. The first two parts of the study assessed PK, safety and tolerability of aramchol tablets administered in single doses of 200 mg, 400 mg and 600 mg either following a ten-hour overnight fast or a high-fat, high-calorie meal. The third part of the study assessed PK, safety and tolerability of aramchol tablets administered in the same three doses as the first two parts of the study for ten consecutive days, in each case within one hour after a light breakfast. We did not observe any serious adverse side effects in the PK and food effect study.

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 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.

Our Development Pipeline

Based on the potential metabolic effects of aramchol, we are considering additional indications with meaningful potential market opportunities, with the view of expanding aramchol's therapeutic applications to cholesterol gallstones and other cholestatic diseases and lipodystrophy, a medical condition characterized by abnormal or degenerative conditions of adipose tissue, or body fat, including the loss of body fat from various regions of the body and its redistribution and accumulation in other areas. 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 Steatohepatis (NASH)	Phase IIb	240 patients	Conduct interim analysis of 120 patients in Phase IIb trial who have completed six months of treatment in the first half of 2016 Release top-line results from Phase IIb trial at the end of 2016
Lipodystrophy (as described below)	Phase IIa, Investigator-Initiated Study	50 patients	Release top-line results in the first half of 2016

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 to date 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 or an increase in low-density lipoproteins (i.e., "bad cholesterol"), 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 and personnel, 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 trial correlating fat reduction in the liver as measured by MRS, an FDA validated and commonly used test for the measurement of liver fat content, with aramchol's effect on inflammation in the liver, MRS may become a non-invasive biomarker that is able to measure the effect of aramchol in patients following treatment with aramchol. Additionally, we intend to co-develop a non-invasive biomarker, which can identify the metabolomic, or a mapping of lipids and proteins in different body components, such as blood and liver tissue, profile for NASH patients responding to aramchol treatment and thus would be able to predict individual responses to aramchol prior to treatment. We believe that such biomarkers 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. On September 29, 2014, we purchased 60 EndoPAT™ devices and accessories from, and entered into a collaboration with, Itamar Medical Ltd., referred to herein as Itamar, to include an assessment of endothelial, or arterial, function in our Phase IIb ARREST Study of aramchol in NASH patients. In the completed Phase IIa study we observed a trend of improvement in endothelial function in patients treated with 300mg. of aramchol. The EndoPAT™ device will allow for a validated, consistent measurement of endothelial function

in all patients participating in the study. As mentioned, NASH patients develop cardiovascular complications and present with endothelial dysfunction as a marker of their propensity for atherosclerosis, or hardening of the arteries. A significant improvement in endothelial function, if found, will provide an additional advantage for patients treated with aramchol and will be a differentiating factor for aramchol among other NASH drugs in development.

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 treatment of NASH currently includes our Phase IIb ARREST Study of aramchol for the treatment of NASH in patients who also suffer from obesity and insulin resistance. If our ARREST Study 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 in the United States and Europe for the treatment of NASH in patients who also suffer from obesity and insulin resistance.

- **Exploring other indications for the use of aramchol, which currently includes the treatment of cholesterol gallstones**. We have commenced an open-label Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones and expect that we will report the top line results in the second half of 2015.

- **Establishing a development and commercialization partnership for aramchol upon completion of our ARREST Study 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 outlicensing 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 One Way Liver Genomics S.L., or OWL, 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. OWL also granted us a right of first refusal, exercisable upon completion of our ARREST Study, to enter into a business transaction with OWL regarding the commercial exploitation of the data generated during the collaboration. Additionally, we purchased 60 EndoPAT™ devices and accessories from and collaborated with Itamar in September 2014 to include an assessment of endothelial, or arterial, function in our ARREST Study of aramchol in NASH patients. Endothelial dysfunction, an early sign of atherosclerosis, is often present in NASH patients. In the Phase IIa study, we observed improvement in endothelial function in patients treated with aramchol. Our ARREST Study is designed to confirm aramchol's positive effect on endothelial function by measuring the endothelial function in all participating patients. In the Phase IIa study, all patients measured their own endothelial function by flow-mediated dilation in one center in Israel. Due to the geographic spread of our ARREST Study, we searched for a validated method to measure endothelial function that would not be dependent upon the test performer. We determined that the EndoPAT™ device is best-suited, easy to operate device for measuring endothelial function and perhaps the only method to measure endothelial function consistently across a number of patients.

- **In-license, develop or acquire 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, develop or acquire other molecules and/or 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.

For more information about the Company, please see our Annual Report on Form 20-F for the year ended December 31, 2014, as filed with the SEC on March 31, 2015, which is incorporated by reference herein.

Risk Factors

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 an operating history limited to clinical development of one product and no approved products. To date, we have focused nearly exclusively on developing our product candidate, aramchol. We have funded our operations to date primarily through proceeds from the private placement of ordinary shares, convertible debt and our initial public offering on March 18, 2014. In addition, we have limited operating 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 currently have no products approved for marketing in the United States or any other jurisdiction and have not generated any revenue from product sales to date. We have incurred operating 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, 2013 and 2014 was approximately $17.5 million and $9.1 million, respectively. As of December 31, 2014, we had an accumulated deficit of $36.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from general and administrative costs associated with our operations.

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, as our lead product candidate, aramchol, is still in clinical development and has not been approved by the FDA, nor has 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, or any other product candidate. We will continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

- initiate and manage additional clinical trials for aramchol, and initiate additional research and development programs;
- seek regulatory approvals for our product candidate, or future product candidates, if any;
- implement internal systems and infrastructures, including, without limitation, hiring of additional personnel as needed and developing sales and marketing functions if and when our product candidate receives applicable regulatory approval;

- seek to in-license additional products or 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 aramchol before it is approved by any applicable regulatory agency, commercialized and/or generates revenue, depending on a number of factors, including our ability to:

- obtain favorable clinical 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, or any other indications, it may not gain market acceptance or achieve commercial success. In addition, we anticipate incurring significant costs associated with seeking regulatory approval and 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 expect our research and development expenses to increase in connection with our planned clinical trials and potential initiation of clinical trials for other indications. In addition, if we obtain marketing approval for aramchol, we will likely initially incur significant expenses associated with sales, marketing and manufacturing by third parties, as well as continued research and development expenses. Furthermore, we expect to incur additional costs associated with operating as a public company. 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.

Our operating history is limited to clinical development of one product, 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. Therefore, 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.

We have not yet commercialized any products and we may never be able to do so, and even if we do, the products may not gain market acceptance.

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 and ongoing management of the condition;

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

We currently estimate that our cash position will support our current clinical trials and operations into 2017, although there is no assurance of this. We will likely need to raise substantial additional capital to fund our operations and to develop aramchol beyond its current development stage, and ultimately commercialize it. In addition, we may choose to expand our current research and development focus, or other clinical operations, which may also require additional capital. As of December 31, 2014, we had a net working capital of $31.8 million and cash and cash equivalents of $23.7 million. Our future capital requirements may be substantial and will depend on many factors including:

- our clinical trial results;

- exploration of the possibility to develop aramchol for the treatment of other conditions or indications, or possible label expansion of aramchol once its approved, if at all, for the treatment of other conditions or indications;

- the cost of filing and prosecuting patent applications and the cost of defending our patents;
- the cost of prosecuting infringement actions against third parties;
- the cost, timing and outcomes of seeking marketing approval of aramchol;
- 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 costs associated with developing and/or in-licensing other research and development programs;
- 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 our existing resources will be sufficient to enable us to maintain our currently planned operations, including our continued product development, into 2017, although there is no assurance of this. We believe these funds will enable us to complete any preparatory clinical and non-clinical work, as well as our planned Phase IIb clinical trial of aramchol for the treatment of patients with NASH in patients suffering from obesity and insulin resistance, which we refer to as our ARREST Study, and Phase IIa clinical trial of aramchol for the treatment of patients with cholesterol gallstones. We will require significant additional funds to initiate and complete additional clinical trials, including but not limited to a possible Phase III pivotal trial for the treatment of patients with NASH, and the FDA and European Medicines Agency, or EMA, approval processes. 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 there are 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 and additional financing may cause significant dilution to our existing shareholders. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay planned or ongoing clinical trials or other

development activities for aramchol.

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 and results of operations.

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 size, duration and scope of future clinical trials;
- the regulatory path of our lead product candidate;
- the results of our clinical tests, 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 a 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
- 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.

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

On February 2, 2014, we underwent a reorganization, or the Reorganization, pursuant to which all of our current 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, our predecessor, transferred the entire share capital of Galmed 2000 Inc., a holdings company incorporated in the British Virgin Islands, or GTTI, to the Company; next, GTTI transferred the entire share capital of Galmed International Limited, a company incorporated in Malta, a European Union, or EU, member state, or GIL, to the Company; then, GIL transferred and assigned all of its intellectual property to Galmed Research and Development Ltd., a newly formed Israeli company, or GRD. GIL held all of the equity rights in and to Galmed Medical Research Ltd., an Israeli company, or GMR. In connection with the Reorganization, we obtained a tax pre-ruling, or the Tax 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 of the Group's intellectual property, including the Company's patent portfolio, GIL and GTTI, is not taxable pursuant to the provisions of Sections 131 and 132 of the Income Tax Ordinance (New Version) — 1961, or 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.

Risks Related to Our Business, Industry and Regulatory Requirements

We depend largely 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 largely 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 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 a New Drug Application, or 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 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 earlier 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, tolerable 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 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 clinical trial process is complex and expensive, and 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 Marketing Authorization Application, or 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. On 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 and in part because the results of clinical trials are inherently uncertain and unpredictable. Regulatory authorities, such as the FDA, may decline to permit a clinical trial to proceed or may suspend a clinical trial that it has previously cleared. 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 duration 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 as a Breakthrough Therapy;

- 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 and exclusion 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.

Clinical trials may also be delayed or terminated as a result of inconclusive or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities, the principal investigator al a site, the IRBs at the sites where such boards are overseeing a trial or the data safety monitoring board, or DSMB, that is overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- irregularities in conducting a clinical trial, including by way of example, failure to conduct the clinical trial in accordance with regulatory requirements or the FDA-cleared 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 many of the risks involved with conducting clinical trials, including but not limited to, increased expense and material 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. To date we have experienced a slight delay of approximately three months in the beginning of enrollment of our ARREST Study. Accordingly, we now expect to release the interim results of our ARREST Study in the first half of 2016, instead of in the second half of 2015 as originally planned.

Furthermore, 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.

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.

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, costs and lack of patient interest in participating in such studies limit its use. As such, only patients with a high risk of NASH, which includes patients with metabolic syndrome and an indication of Non-Alcoholic Fatty Liver Disease, or NAFLD, are sent for liver biopsy. Because NASH tends to be 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 aramchol's 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 becomes available, as to which there can be no assurance.

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 that the clinical data confirms that the drug is both safe and effective for its intended use, 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, without limitation, the fact that:

- 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 required 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 require 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 both the Phase IIb and Phase III 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 these additional Phase IIb or Phase III clinical 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 data from these additional studies 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 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, without limitation:

- regulatory authorities may suspend or withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings, so-called "black box warnings," contraindications or restrictions on the product's intended use;
- 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 potential Phase III clinical trials, even if all endpoints are met, will support regulatory approval of aramchol for the treatment of NASH.

Although progress has been made as indicated below, 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, notwithstanding this progress, the development pathway for aramchol is not entirely clear beyond Phase IIb, as no official guidelines have been published to date.

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 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.

Although the FDA has indicated at a workshop held in association with AASLD, and in the subsequent joint publication, that an acceptable surrogate endpoint for drugs targeting the early stages of NASH (i.e., fat infiltration and inflammation, as opposed to fibrosis) is resolution 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 resolution of NASH in liver biopsy, the FDA will require longer-term studies of aramchol, such as Phase IV studies, 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 regulatory risks or new requirements.

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 affect 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 the approved product, withdrawal of FDA approval of the previously approved product, or voluntary withdrawal from the marketplace of the approved product. 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:

- suspension or imposition of restrictions on operations, including costly new manufacturing requirements;
- refusal to approve pending applications or supplements to applications;
- suspension of any ongoing clinical trials;
- suspension or withdrawal of marketing approval;
- an injunction or imposition of civil or criminal penalties or monetary fines;
- seizure or detainment of products;
- banning or restriction of imports and exports;
- issuance of warning letters or untitled letters;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- refusal to approve pending applications or supplements to applications.

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.

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 will increase and our ability to out-license product candidates may be impeded.

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, without limitation:

- 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 to or post-regulatory approval.

A failure to timely and effectively address the additional risks related to entering into or maintaining international business relationships could have a material adverse effect on our business, liquidity operating results and financial condition.

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, without limitation:

- 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;
- 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 as reflected in the product's approved labeling. In particular, any labeling approved by FDA or other foreign regulatory agencies for aramchol necessarily limits its use for certain conditions in certain patient populations. Also, 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 or knowingly acquiesced in 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 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 U.S. Congress, or 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 Modernization Act, changed the way Medicare covers and pays for most pharmaceutical products in a number of ways. Medicare is the single largest third-party payment program and is administered by the Centers for Medicare & Medicaid Services, or CMS. Medicare traditionally covered prescription drugs administered by physicians. The Modernization Act introduced a new reimbursement methodology based on average sales prices for many of these drugs. The Modernization Act also established a new competitive acquisition program for the purchase of Part B drugs. This program, when fully implemented, will likely reduce the prices of these drugs. While the Medicare provisions of the Modernization Act 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.

Most notably, the Modernization Act also expanded coverage through a new Part D to include ordinary self-administered outpatient drugs. Medicare part D though operates through private insurers, and these insurers negotiate prices with pharmacies and with manufacturers. Intense negotiations can result in reduced revenues to manufacturers.

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 U.S. Congress, or 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 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' Medicaid 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. The rebate on innovator drugs is the greater of 23.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on a launch date and current quarter AMP. The total rebate amount for innovator drugs is capped 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 were also been enacted, which may affect our business practices with healthcare practitioners. 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 and Medicaid programs, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created 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. Further, the Deficit Reduction Act of 2010, directed CMS to contract a vendor to determine "retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)." This survey information can be used to determine the National Average Drug Acquisition Cost, or NADAC. Some states have indicated that they will reimburse based on the NADAC and this can result in further reductions in the prices paid for various outpatient drugs.

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. It will be difficult for us to profitably sell aramchol if reimbursement for the product is limited by government authorities or 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 coverage or reimbursement will be available for aramchol and, if coverage and reimbursement are available, the extent of coverage and the level of reimbursement. Reimbursement may affect 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 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. In addition, 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.

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 and certain hospitals 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 and again in 2009 and 2010 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, and 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, if at all.

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 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 could 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 than us, with significantly greater resources and more experience than us. 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. and Gilead Sciences, Inc. 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.

We face potential product and other 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, among other things:

- 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 studies to date indicate that aramchol is safe and well-tolerated at single doses up to 900 mg, at doses up to 600mg administered once-daily for up to ten days and at doses up to 300 mg administered once-daily for up to three months, there were incidences of non-serious adverse events in four completed and fully analyzed clinical trials. Those four studies enrolled 168 patients.

In our Phase Ia clinical trial we enrolled 17 healthy volunteers. A total of 34 adverse events were reported in nine subjects. All adverse events were mild or moderate and transient and resolved without sequelae. There were no serious adverse events, deaths or other significant adverse events observed in this study.

In our Phase Ib placebo-controlled clinical trial with 25 healthy and mildly overweight male volunteers a total of 64 adverse events were reported by 80% of the patients. A higher proportion of patients reported drug-related adverse events in the placebo group (88.9%) compared to the 30 mg active group (55.6%) and the 300 mg active group (71.4%). All adverse events were mild or moderate and resolved without sequelae. There were no serious adverse events, deaths or other significant adverse events.

We completed a pharmacokinetic, or PK, and food effect study in 66 healthy male volunteers consisting of three parts. Overall, over the three parts of the study, the vast majority of adverse events were mild and unrelated to aramchol and all of the adverse events were transient and gave no indication of target organ toxicity. All doses of aramchol administered during the study were safe and well-tolerated. No serious adverse events or deaths occurred during the study. No clinically significant abnormalities related to any aramchol dose were noted in electrocardiograms, or ECGs, laboratory results, vital signs or physical examinations.

In our Phase IIa placebo-controlled trial with 60 patients with steatosis due to NAFLD or NASH, most adverse events were mild and transient, except for three (mild asthenia, mild nausea and moderate back pain), which were initially considered to be related to the study drug; however, after unblinding the study results it was found that the three adverse events occurred in the placebo group. There was one serious adverse event reported, acute appendicitis that was unrelated to study drug, which occurred in a patient taking the placebo. The patient fully recovered from the serious adverse event without sequelae and completed the study treatment. There were no deaths or other significant adverse events reported in this study.

If we are unable to obtain adequate insurance to protect our business and property against damage, and from any losses or claims from third parties, our financial condition could be adversely affected in the event of uninsured or inadequately insured loss or damage. 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.

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

We have obtained insurance coverage for our clinical trials in accordance with market standards and in compliance with applicable Israeli law. 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 President and 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.

Additionally, 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 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.

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 Jumpstart Our Business Startups Act of 2012, or 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 our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 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, our independent public accountant has 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 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, among other things:

- 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

- 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, including our ability to raise capital, 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.

Moreover, in past years, the U.S. and global economies have taken a 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, 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.

The Israeli Ministry of Health may not permit us to conduct multiple biopsies as contemplated in our ARREST Study of aramchol in Israel.

On March 9, 2015, we announced that we had begun the enrollment stage of our Phase IIb ARREST Study of aramchol in 240 biopsy-diagnosed NASH patients. While the primary endpoint of the study is a significant reduction of liver fat, as measured by magnetic resonance spectroscopy, or MRS, the main secondary endpoint of the ARREST Study is resolution of NASH on biopsies, which can be assessed only at the completion of the study and by repeated liver biopsies. We are conducting a portion of our ARREST Study in Israel. While, the Israeli Ministry of Health has granted us approval to conduct our ARREST Study in 14 centers in Israel, it has taken exception to the necessity of conducting a second biopsy at the end of the trial period, as specified by the trial protocol. As this position is inconsistent with the already established guidance by the FDA and the EMA, it was unexpected. We are not expecting that the Israeli Ministry of Health will reverse its preliminary position and, as such, we reconfigured our recruitment targets in Israel to include patients who have undergone liver biopsies no more than six months prior to enrolling in the ARREST Study. However, there is still a possibility of the Israeli Ministry of Health reversing its preliminary position as multiple parties unrelated to us, including leading Israeli hematologists and gastroenterologists, are conducting ongoing discussions with the Israeli Ministry of Health to attempt to convince it to reconsider its original position for a variety of reasons. Notwithstanding the foregoing, we will also continue a close dialogue with the Israeli Ministry of Health, especially after we obtain the interim results from the ARREST Study, to continuously assess the Israeli Ministry of Health's willingness to allow a second biopsy.

Contemporaneously, we also announced on March 9, 2015 that we had expanded our clinical activities to include patient recruitment for the ARREST Study in the United States. Professor Vlad Ratziu, from the University Pierre et Marie Curie in Paris, an internationally acclaimed key opinion leader, is the ARREST Study's global principal investigator, and Professor Rohit Loomba, from the University of California San Diego School of Medicine, is the ARREST Study's U.S.-based principal investigator. We expanded our patient recruitment into the United States because we believe that U.S.-based patient recruitment will shorten the recruitment time for our ARREST Study, especially considering the Israeli Ministry of Health's current position on the requirement of a second liver biopsy. We also believe that expanding our clinical activities into the United States will improve the ARREST Study's breadth and relevance, including potentially allowing us to immediately commence Phase III clinical trials in NASH in the United States without any addition clinical requirements, although there is no assurance.

Phase IIb clinical operations in the United States may divert a significant amount of Company resources and may ultimately be unsuccessful.

We are expanding our clinical operations for Phase IIb to the United States, which will require significant time, funds and Company resources. We believe that the United States has a larger population of potential patients from which we can recruit for our ARREST Study than Israel, and we believe that the FDA is more likely to accept our trial protocol which requires repeated liver biopsies than the Israeli Ministry of Health. In March 2015, we submitted to the FDA an update of our existing Investigational New Drug, or IND, filing, in order to initiate the ARREST Study in the United States. However, there is no assurance that the FDA will clear our updated IND request. Furthermore, even if the FDA

clears our updated IND request, we may not have the time, funds or resources necessary to complete the ARREST Study in the United States. Moreover, even to the extent the ARREST Study is conducted, such study may ultimately prove to be unsuccessful.

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 API. 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 aramchol or the aramchol API manufacturing processes. 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, 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. Moreover, collaborations with pharmaceutical or biotechnology companies and other third parties are often terminated or allowed to expire by the other party. Any lack of effort or ability by our collaborators or any such disagreement, 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 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 rights that are sufficiently broad and protective could impact our ability to compete effectively.

To compete effectively, we must 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. We cannot predict the scope and extent of patent protection for aramchol because the patent positions of pharmaceutical products are complex and uncertain. 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, but are not limited to, 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;
- any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
- we may not be able to develop additional proprietary technologies that are patentable;
- 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;
- other companies may challenge and invalidate patents licensed or issued to us or our customers;
- a court could determine that a competitor's technology or product does not infringe our patents;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- 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;
- enforcement of patents is complex, uncertain and expensive, and our patents may be found invalid or enforceable;
- 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 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 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 aramchol's 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.

Our potential development of aramchol salts may not result in improved bioavailability compared to the existing form of aramchol. Furthermore, although we have submitted patent applications for our aramchol salts in development, there is no assurance that we will receive any patents for them, and even if we receive one or more patents for our aramchol salts in development, they may be of little or no commercial value.

As part of our ongoing pre-formulation studies, we have confirmed that several aramchol salts have improved solubility and intestinal permeability as compared to the existing form of aramchol. We have recently submitted new patent applications to protect such salts. In addition, we intend to plan and conduct further formulation development in order to test the possibility of using aramchol salts in future clinical studies. 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 study, or studies of the biological equivalence of two proprietary preparations of a drug, prior to administering an aramchol salt formulation to patients in our clinical studies.

If we commence animal PK studies and formulation development in order to test the bioavailability of the aramchol salt compounds, the results might not support the claims sought by us. Success in our earlier pre-formulation studies does not ensure that later studies will be successful, and the results of later studies may not replicate the results of our prior pre-formation studies. Furthermore, either or both of the animal PK and formulation development studies may fail to demonstrate that the aramchol salts result in an improvement in solubility and bioavailability. Any such failure may cause us to abandon the aramchol salt compounds and may delay development of other product candidates. If the animal PK studies do not support our claims, the completion of development of such potential product candidates may be significantly delayed or abandoned, which will significantly impair our ability to generate revenues and will materially adversely affect our results of operations.

There can be no assurance that the U.S. Patent and Trademark Office, or the USPTO, will issue any patents based on the patent applications that we submitted to protect our aramchol salts, nor, should the USPTO issue any patents to us with respect to the aramchol salts, that we will be provided with adequate protection against potentially competitive

products. Furthermore, if the USPTO issues us one or more patents for the aramchol salts, there can be no assurance that the issued patents will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent these patents in the United States or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

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 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.

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, or our employment and consulting agreements contain non-competition provisions. These agreements, to the extent they are in place and in effect, 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 provides that if there is no agreement that 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. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. Recent decisions by the Compensation and Rewards Committee and Israeli courts have created some uncertainty in this area, as it was held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

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.

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 Ownership of Our Ordinary Shares and this Offering

The market price of our ordinary shares is volatile and you may sustain a complete loss of your investment.

Since our initial public offering, the trading price of our ordinary shares has been volatile and is likely to continue to be volatile. In addition, the trading volume is and has been volatile and sometimes relatively illiquid. 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 and trading volume of our ordinary shares:

- inability to obtain the approvals necessary to commence further clinical trials;
- delays in existing clinical trials due to an inability to enroll patients at the expected pace, among other factors;
- unsatisfactory or inconclusive 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;

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- success of research and development projects;
- 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 and trading volume 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. Any adverse determination in litigation could also subject us to significant liabilities.

Moreover, the liquidity of our ordinary shares is 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 are 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.

Our principal shareholders, President and Chief Executive Officer and directors currently own approximately 39.7% of our outstanding ordinary shares on a fully diluted basis. They will therefore be able to exert significant control over

matters submitted to our shareholders for approval.

Our President and Chief Executive Officer, directors and shareholders that own more than 5% of our outstanding ordinary shares own approximately 39.7% of our ordinary shares on a fully diluted basis. 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.

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. Prior to the consummation of our initial public offering and in accordance with the terms of the Tax Pre-Ruling, the holders of substantially all of our then-outstanding ordinary shares and options agreed, 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 period. 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.

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, at-the-market issuances, 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 use of the offering proceeds may not yield a favorable return on your investment.

We currently anticipate that the net proceeds from this offering will be used primarily for Phase III clinical development of aramchol. In addition, we may also use such proceeds for further clinical and pre-clinical development and general corporate purposes. Pending the application of the net proceeds, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as corporate debt securities, and certain short-term money market investments, including cash, short term cash and cash equivalents in accordance with our current cash management strategy. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. Pending the use of the proceeds in this offering, we will invest them. However, the proceeds may not be invested in a manner that yields a favorable or any return.

Our U.S. shareholders may suffer adverse tax consequences due to our classification 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. Based upon our review of our financial data, we have determined that we are currently a PFIC, and we likely will continue to be a PFIC, at least until we develop a source of significant operating revenues. 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 “Item 10. Additional Information—Taxation— Certain U.S. Federal Income Tax Considerations” of the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015) 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.

If we are unable to satisfy the requirements of Section 404 as they apply to a foreign private issuer and emerging growth company, 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 became subject to the requirements of the Sarbanes-Oxley Act when our ordinary shares were 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 are not be required to comply with the auditor attestation requirements of Section 404 for up to five fiscal years after the date of our initial public offering. See "Item 5. Operating and Financial Review and Prospects—Jumpstart Our Business Startups Act of 2012" of our Annual Report on Form 20-F, as filed with the SEC on March 31, 2015, for more detail regarding our status as an emerging growth company.

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 is 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, 5759-1999, as amended, or the Companies Law, imposes certain restrictions on our ability to declare and pay dividends.

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act, the listing requirements of the Nasdaq Capital Market, 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 incurred and will continue to 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. 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 and will continue to make changes to our corporate governance standards, compensation policy, 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 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 "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 President and 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 to and currently do 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 to, and currently do, 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 currently 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.

In addition, as a "foreign private issuer," we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements and certain individual executive compensation information, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. 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 reduce the frequency and scope of information and protections to which you are entitled as an investor.

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 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.

Our ordinary shares are listed 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.

Our ordinary shares are listed 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 the winter of 2008-2009, the autumn of 2012 and the summer of 2014, Israel was engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip. The last conflict, as well as the previous round of escalation, involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees, service providers and some of our consultants are located. During the summer of 2006, Israel was also engaged in armed conflicts with Hezbollah, a Lebanese Islamist Shiite militia group and political party, which also involved missile strikes against civilian targets in the northern part of Israel. The continuation of such strikes may negatively affect business conditions in Israel.

Since February 2011, riots and uprisings in several countries in the Middle East and neighboring regions have led to severe political instability in several neighboring states and to a decline in the regional security situation. Such instability may affect the local and global economy, could negatively affect business conditions and, therefore, could adversely affect our operations. To date, these matters have not had any material effect on our business and results of operations; however, the regional security situation and worldwide perceptions of it are outside our control, and there can be no assurance that these matters will not negatively affect us in the future. 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 subjects of economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies

may have an adverse impact on our operating results, financial 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, 2014 was $1.00 = Euro 0.83 and $1.00 = NIS 3.89. 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 2012, 2013 or 2014.

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, which ends in February 2016, 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 our initial public 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 sold in our initial public 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 “Item 10. Additional Information—E. Taxation—Certain Israeli Tax Considerations—Pre-Ruling Regarding a Reorganization of Our Corporate Structure” of the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015, 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 of association, or 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.

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.

Our Articles 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.

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.

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 controlling shareholder, a shareholder who knows that it possesses the power to determine the outcome of a shareholders' vote or a shareholder who has the power 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. 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.

Cautionary Note Regarding Forward-Looking Statements

This Registration Statement on Form F-3 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," "anticipate," "could," "might," "seek," "project," "forecast," "continue" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements may be included in, among other things, 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:

- U.S. Food and Drug Administration, or FDA, approval of, or European Medicines Authority, or EMA, or other regulatory action with respect to, our product candidate, 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 our expectations regarding the commercial market of patients with cholesterol gallstones;
- third-party payor reimbursement for aramchol;
- our estimates regarding anticipated capital requirements and our needs for additional financing;
- 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;
- 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 development and approval of the use of aramchol for additional indications or in combination therapy; and
- our expectations regarding licensing, acquisitions and strategic operations.

We believe these forward-looking statements are reasonable; however, 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 Form F-3 in greater detail under the heading "Risk Factors." 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 Form F-3. 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.

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 to the best of our knowledge 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.

Offer Statistics and Expected Timetable

We may sell from time to time pursuant to this prospectus (as may be detailed in prospectus supplements) an indeterminate number of ordinary shares as shall have a maximum aggregate offering price of $150,000,000. The actual per share price of the ordinary shares that we will offer pursuant hereto will depend on a number of factors that may be relevant as of the time of offer (see "Plan of Distribution" below).

Capitalization and Indebtedness

The following table sets forth, on the basis of generally accepted accounting principles in the United States, our consolidated capitalization and indebtedness as of December 31, 2014. There has been no material change in the Company's capitalization and indebtedness since December 31, 2014.

	U.S. Dollars (In thousands)
Short-term borrowings	-
Long-term borrowings	-
Shareholders' equity:	
Ordinary shares, NIS 0.01 par value, 50,000,000 authorized shares; 11,100,453 outstanding shares	32
Additional paid-in capital	68,116
Accumulated other comprehensive income	4
Accumulated deficit	(36,745)
Total shareholders' equity	31,407
Total capitalization and indebtedness	31,407

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Reasons for the Offer and Use of Proceeds

Our management will have broad discretion over the use of the net proceeds from the sale of our securities pursuant to this prospectus. Unless otherwise indicated in any accompanying prospectus supplement, we currently intend to use the net proceeds from the sale of the securities offered pursuant to this prospectus for: (i) Phase III clinical development of aramchol; (ii) further clinical and pre-clinical development; and (iii) general corporate purposes.

Price RanGe of Our Shares

Our ordinary shares are listed on the NASDAQ Capital Market under the symbol “GALM” following our initial public offering in the United States in May 2014. The following table shows the high and low sales prices for our ordinary shares during the indicated periods.

Period	High (U.S. $)	Low (U.S. $)
Five Most recent full financial years (as applicable):		
December 31, 2014	6.16	5.60
Six most recent months:		
October 2014	8.56	6.09
November 2014	6.87	5.33
December 2014	6.85	4.58
January 2015	8.99	5.54
February 2015	10.00	6.33
March 2015 (through and including March 26)	13.50	8.28
Two most recent full financial years and subsequent periods, by quarter (as applicable):		
First Quarter 2014 (beginning March 13)	18.73	10.85
Second Quarter 2014	12.44	6.38
Third Quarter 2014	11.48	5.83
Fourth Quarter 2014	8.56	4.58
First Quarter 2015	11.00	5.54

On March 26, 2015, the closing price of our ordinary shares on the NASDAQ Capital Market was $10.31.

Plan of Distribution

Securities and Exchange Commission rules limit the usage of the registration statement of which this prospectus forms a part. Assuming that the aggregate worldwide market value of our common equity held by non-affiliates remains below $75 million, we may only sell, pursuant hereto, such number of ordinary shares, which constitutes, together with all other ordinary shares sold pursuant to the registration statement of which this prospectus forms a part, or any similar primary offering under a registration statement on Form F-3, during the period of 12 calendar months immediately prior to, and including, such sale, no more than one-third (1/3) of the worldwide aggregate market value of our common equity held by non-affiliates. Based on the closing sale price of our ordinary shares on the Nasdaq Capital Market on March 13, 2015, which was $9.26, and a total of 6,634,319 outstanding ordinary shares held by non-affiliates as of such date, the aggregate worldwide market value of our outstanding ordinary shares held by non-affiliates as of such date was $61,433,794. As of the date hereof, we have not offered any securities pursuant to the registration statement of which this prospectus forms a part or any similar registration statement during the prior 12 calendar month period that ends on and includes the date hereof.

We may sell the offered ordinary shares on a negotiated or competitive bid basis to or through underwriters or dealers. We may also sell the ordinary shares directly to institutional investors or other purchasers or through agents. We will identify any underwriter, dealer, or agent involved in the offer and sale of the ordinary shares, and any applicable commissions, discounts and other terms constituting compensation to such underwriters, dealers or agents, in a prospectus supplement. We may distribute our ordinary shares from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of our securities offered by the prospectus supplement.

If underwriters are used in the sale of our ordinary shares, such shares will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Unless stated otherwise in a prospectus supplement, the obligation of any underwriters to purchase our ordinary shares will be subject to certain conditions

and the underwriters will be obligated to purchase all of the applicable shares if any are purchased. If a dealer is used in a sale, we may sell our ordinary shares to the dealer as principal. The dealer may then resell the shares to the public at varying prices to be determined by the dealer at the time of resale. In effecting sales, dealers engaged by us may arrange for other dealers to participate in the resales.

We or our agents may solicit offers to purchase ordinary shares from time to time. Unless stated otherwise in a prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. In addition, we may enter into derivative sale or forward sale transactions with third parties, or sell ordinary shares not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with such transaction, the third parties may, pursuant to this prospectus and the applicable prospectus supplement, sell ordinary shares covered by this prospectus and the applicable prospectus supplement. If so, the third party may use shares borrowed from us or others to settle such sales and may use shares received from us or others to close out any related short positions. We may also loan or pledge shares covered by this prospectus and the applicable prospectus supplement to third parties, who may sell the loaned shares or, in the event of default in the case of a pledge, sell the pledged shares pursuant to this prospectus and the applicable prospectus supplement. The third party in such transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

In connection with the sale of our ordinary shares, underwriters or agents may receive compensation (in the form of discounts, concessions or commissions) from us or from purchasers of securities for whom they may act as agents. Underwriters may sell ordinary shares to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of our ordinary shares may be deemed to be “underwriters” as that term is defined in the Securities Act of 1933, or the Securities Act, and any discounts or commissions received by them from us and any profits on the resale of the shares by them may be deemed to be underwriting discounts and commissions under the Securities Act. Compensation as to a particular underwriter, dealer or agent might be in excess of customary commissions and will be in amounts to be negotiated in connection with transaction involving our ordinary shares. We will identify any such underwriter or agent, and we will describe any such compensation paid, in the related prospectus supplement. Maximum compensation to any underwriters, dealers or agents will not exceed any applicable FINRA limitations.

Underwriters, dealers and agents may be entitled, under agreements with us, to indemnification against and contribution toward certain civil liabilities, including liabilities under the Securities Act.

If stated in a prospectus supplement, we will authorize agents and underwriters to solicit offers by certain specified institutions or other persons to purchase our ordinary shares at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specific date in the future. Institutions with whom such contracts may be made include commercial savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions, and other institutions, but shall in all cases be subject to our approval. Such contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth the commission payable for solicitation of such contracts. The obligations of any purchase under any such contract will be subject to the condition that the purchase of the ordinary shares shall not be prohibited at the time of delivery under the laws of the jurisdiction to which the purchaser is subject. The underwriters and other agents will not have any responsibility in respect of the validity or performance of such contracts.

If underwriters or dealers are used in the sale, until the distribution of our ordinary shares is completed, SEC rules may limit the ability of any such underwriters and selling group members to bid for and purchase the shares. As an exception to these rules, representatives of any underwriters are permitted to engage in certain transactions that stabilize the price of the shares. Such transactions may consist of bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares. If the underwriters create a short position in the ordinary shares in connection with the offering (in other words, if they sell more shares than are set forth on the cover page of the prospectus supplement), the representatives of the underwriters may reduce that short position by purchasing shares in the open market. The representatives of the underwriters also may elect to reduce any short position by exercising all or part of any over-allotment option we may grant to the underwriters, as described in the prospectus supplement. In addition, the representatives of the underwriters may impose a penalty bid on certain underwriters and selling group members. This means that if the representatives purchase shares in the open market to reduce the underwriters' short position or to stabilize the price of our ordinary shares, they may reclaim the amount of the selling concession from the underwriters and selling group members who sold those shares as part of the offering. In general, purchases of a security for the purpose of stabilizing or to reduce a short position could cause the price of the security to be higher than it might be in the absence of such purchases. The imposition of a penalty bid might also have the effect of causing the price of the securities to be higher than it would otherwise be. If commenced, the representatives of the underwriters may discontinue any of the transactions at any time. These transactions may be effected on any exchange on which our ordinary shares are traded, in the over-the-counter market, or otherwise.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named

in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

Certain of the underwriters or agents and their associates may engage in transactions with and perform services for us or our affiliates in the ordinary course of their respective businesses.

Expenses

We are paying all of the expenses of the registration of our securities under the Securities Act , including registration and filing fees, printing and duplication expenses, administrative expenses, accounting fees and the legal fees of our counsel. We estimate these expenses to be approximately $81,430 which at the present time include the following categories of expenses:

Fee/Expense	Amount (U.S. $)
SEC registration fee	$17,430
Legal fees and expenses	$49,000
Accounting fees and expenses	$12,000
Miscellaneous expenses	$3,000
Total	$81,430

In addition, we anticipate incurring additional expenses in the future in connection with the offering of our securities pursuant to this prospectus. Any such additional expenses will be disclosed in a prospectus supplement.

Legal Matters

The validity of the securities being offered hereby will be passed upon for us by Tulchinsky, Stern, Marciano, Cohen, Levitski & Co., Tel Aviv, Israel. DLA Piper LLP (US), Short Hills, New Jersey, is acting as our counsel in connection with United States securities laws.

Experts

The financial statements incorporated in this prospectus by reference from the Company’s Annual Report on Form 20-F for the year ended December 31, 2014, as filed with the SEC on March 31, 2015, have been audited by Brightman Almagor Zohar & Co., a member of Deloitte Touche Tohmatsu Limited, an independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Memorandum and Articles of Association

Our original articles of association were registered with the Israeli Registrar of Companies at the time of incorporation of the Company on July 31, 2013, under our registration number 51-495351-2. At the 2014 annual general meeting of shareholders, our shareholders adopted our Articles, which became effective on the consummation of our initial public offering in the United States in March 2014, whereby the Company became a public company under the Companies Law. Under the Articles, the purpose of the Company is to engage in any lawful activity.

The following description of our share capital and provisions of our Articles are summaries and do not purport to be complete and are qualified in their entirety by the complete text of the Articles, which are filed as exhibits to this report and incorporated by reference herein, and by Israeli law.

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.

Under the Articles, a director shall vacate his or her office if that director dies; is declared bankrupt; is declared to be legally incompetent; resigns such office by notice in writing given to the Company; is not re-elected by the shareholders upon expiration of his or her term at the relevant annual general meeting of shareholders; or otherwise as provided in the Companies Law.

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.

For discussions relating to certain compensation-related requirements of the Companies Law, external directors and financial experts, committees of the Board, and exculpation and indemnification of directors and officers, see "Item 6 - Directors, Senior Management and Employees" in the Company's Annual Report on Form 20-F, as filed with the SEC on March 31, 2015.

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 "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management" in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015, 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.

Approval Procedure

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 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 Office Holders' Terms of Office and Employment (which includes compensation, indemnification or insurance) generally require the approval of the remuneration committee, board of directors and, in certain circumstances, the shareholders, in that order, and must generally be consistent with the Company's Compensation Policy, as described under "Item 6—Directors, Senior Management and Employees—B. Compensation" of the Company's Annual Report on Form 20-F, as filed with the SEC on March 31, 2015.

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.

Transactions with 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.

Under the Companies Law, an Extraordinary Transaction is defined as any of the following: (i) a transaction other than in the ordinary course of business; (ii) a transaction that is not on market terms; or (iii) a transaction that may have a material impact on a company's profitability, assets or liabilities.

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 by a Special Majority, in that order.

Arrangements regarding the Terms of Office and Employment 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 a Special Majority, in that order, as further described under "Item 6—Directors, Senior Management and Employees—B. Compensation" in the Company's Annual Report on Form 20-F, as filed with the SEC on March 31, 2015, with respect to Office Holders' compensation.

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.

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.

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, declared as enemies of Israel.

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. According to regulations promulgated pursuant to the Companies Law and governing the terms of notice and publication of shareholder meetings of public companies, or the General Meeting Regulations, holder(s) of one percent or more of the Company's voting rights may propose any matter appropriate for deliberation at a shareholder meeting to be included on the agenda of a shareholder meeting, generally by submitting a proposal within seven days of publicizing the convening of a shareholder meeting, or, if the Company publishes a preliminary notice at least 21 days prior to publicizing the convening of a meeting (stating its intention to convene such meeting and the agenda thereof), within fourteen days of such preliminary notice. Any such proposal must further comply with the information requirements under applicable law and the Articles.

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.

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;
- 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.

Mergers and Acquisitions under Israeli Law

(i) 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 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.

(ii) 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.

(iii) 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.

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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 date hereof, no preferred shares are 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 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

On July 31, 2013, the Company's incorporation date, the registered share capital of the Company was NIS 500,000 divided into 50,000,000 ordinary shares, NIS 0.01 par value per share.

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.

Material COntracts

The following are summary descriptions of certain material agreements to which we are a party. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to our Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015.

For a description of our material agreements relating to our strategic collaborations and research arrangements and other material agreements, please refer to "Item 4.B. Information on the Company—Business Overview—Strategic Collaborations, Research Arrangements and other Material Agreements" in the Company's Annual Report on Form 20-F, as filed with the SEC on March 31, 2015. In addition, we have previously entered into the agreements described below, but we no longer deem these to be material to the Company

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 ARREST Study 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 ARREST Study, 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, and at this stage we have no intention to pursue such an agreement. 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 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 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 and at this stage we have no intention to pursue such an agreement.

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 ARREST Study 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 PARREST Study, 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 and at this stage we have no intention to pursue such an agreement. The Enterome MOU is silent as to term, termination and whether or not it is binding.

Employment Agreements

See “Item 6. Directors, Senior Management and Employees—B. Compensation—Employment Agreements and Arrangements with Directors and Related Parties” in the Company’s Annual Report on Form 20-F, as filed with the SEC on March 31, 2015.

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, declared as enemies of Israel or otherwise as set forth under “Item 10. Additional Information—E. Taxation” in the Company’s Annual Report on Form 20-F, as filed with the SEC on March 31, 2015.

Taxation

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

Certain 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 companies (as defined below), such as the Company, are generally subject to corporate tax at the rate of 26.5% of their taxable income, as of January 1, 2014 (and 25% in 2013).

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.

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 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%, unless the Preferred Enterprise is located in a specified development zone, in which case the rate will be 9%. 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.

As of January 1, 2014, dividends paid out of income attributed to a Preferred Enterprise are subject to withholding tax at source at the rate of 20% unless a different tax rate is provided under an applicable tax treaty. 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. Beginning in 2013, an additional tax at a rate of 2% may be imposed upon shareholders whose annual taxable income from all sources exceeds a certain amount.

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 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, beginning in 2013, an additional tax at a rate of 2% may be imposed upon shareholders whose annual taxable income from all sources exceeds a certain amount.

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

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our 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.

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 U.S.-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 "Item 4. Information on the Company—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, which ends in February 2016, 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.

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 and guidelines issued by the Israeli Tax Authorities:

- *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; 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, which included our initial public 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 the initial public offering.

Certain U.S. Federal Income Tax Considerations

The following is a general summary of 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 hold our ordinary shares as capital assets. This summary is based on the U.S. Internal Revenue Code of 1986, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, the income tax treaty between the United States and Israel, or 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 retroactive effect, or to different interpretation. No ruling has been sought from the U.S. Internal Revenue Service, or 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 and does not constitute tax advice. 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, qualified retirement plans, individual retirement accounts or other tax-deferred accounts, regulated investment companies, partnerships, or other entities treated as partnerships for U.S. federal income tax purposes, 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

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. However, we may not determine our earnings and profits under U.S. federal income tax principles, in which case U.S. Holders should expect the entire amount of any distribution to be treated as a dividend.

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 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, 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.

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 discussed below under "Passive Foreign Investment Company," we have determined that we are a PFIC and likely will continue to be a PFIC, at least until we develop a source of significant operating revenues.

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 (determined under U.S. federal income tax rules) 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%) 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.

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. Based upon our review of our financial data, we have determined that we are currently a PFIC, and we likely will continue to be a PFIC, at least until we develop a source of significant operating revenues.

U.S. Holders should be aware of certain tax consequences of investing directly or indirectly in us due to our classification as 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 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 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. See the discussion regarding Form 8621, Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, above.

In addition, certain U.S. Holders are required 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.

Net Investment Income Tax

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, 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, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Documents on Display

You may read and copy this 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.

As a "foreign private issuer," we are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements 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 are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and "short-swing" profit recovery provisions contained in Section 16 of the 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.

We 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 the Company's Annual Report on Form 20-F, as filed with the SEC on March 31, 2015, and does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Material Changes

Except as otherwise described in our Annual Report on Form 20-F for the fiscal year ended December 31, 2014, and in our Reports on Form 6-K filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act and incorporated by reference or disclosed herein, no reportable material changes have occurred since December 31, 2014.

Where You can find More Information and Incorporation of Information by Reference

We are an Israeli company and are a "foreign private issuer" as defined in Rule 3b-4 under the Exchange Act. As a result, (1) our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act, (2) transactions in our equity securities by our officers and directors are exempt from Section 16 of the Exchange Act, and (3) until November 4, 2002, we were not required to make our SEC filings electronically, so that many of those filings are not available on the Commission's website. However, since that date, we have been making all required filings with the Commission electronically, and these filings are available over the Internet as described below.

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In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we file with the Commission an Annual Report on Form 20-F containing financial statements audited by an independent registered public accounting firm. We also furnish reports on Form 6-K containing unaudited financial information for the first three quarters of each fiscal year and other material information that we are required to make public in Israel, that we file with, and that is made public by, any stock exchange on which our shares are traded, or that we distribute, or that is required to be distributed by us, to our shareholders.

You can read and copy any materials we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can obtain information about the operation of the SEC Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains information we file electronically with the SEC, which you can access over the Internet at http://www.sec.gov. You may also access the information we file electronically with the SEC through our website at http://www.galmedpharma.com/. The information contained on, or linked from our website does not form part of this prospectus.

This prospectus is part of a registration statement on Form F-3 filed by us with the SEC under the Securities Act. As permitted by the rules and regulations of the SEC, this prospectus does not contain all the information set forth in the registration statement and the exhibits thereto filed with the SEC. For further information with respect to us and the ordinary shares offered hereby, you should refer to the complete registration statement on Form F-3, which may be obtained from the locations described above. Statements contained in this prospectus or in any prospectus supplement about the contents of any contract or other document are not necessarily complete. If we have filed any contract or other document as an exhibit to the registration statement or any other document incorporated by reference in the registration statement, you should read the exhibit for a more complete understanding of the document or matter involved. Each statement regarding a contract or other document is qualified in its entirety by reference to the actual document.

We incorporate by reference in this prospectus the documents listed below, and any future Annual Reports on Form 20-F or Reports on Form 6-K (to that extent that such Form 6-K indicates that it is intended to by incorporated by reference herein) filed with the SEC pursuant to the Exchange Act prior to the termination of the offering. The documents we incorporate by reference include our Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015.

The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede the information contained in this prospectus.

We shall provide you without charge, upon your written or oral request, a copy of any of the documents incorporated by reference in this prospectus, other than exhibits to such documents which are not specifically incorporated by reference into such documents. Please direct your written or telephone requests to us at Galmed Pharmaceuticals Ltd.,

8 Shaul Hamelech Blvd., Amot Mishpat Bldg., Tel Aviv, Israel 6473307, Tel: 972.3.693.8448, Fax: 972.3.693.8447; Attn: Allen Baharaff, President and Chief Executive Officer.

Enforcability of Civil Liabilities

Service of process upon us and upon our directors and officers and the experts named in his prospectus, most of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because a major portion of our assets and most of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

There is doubt as to the enforceability of civil liabilities under the Securities Act and the Exchange Act in original actions instituted in Israel. However, subject to specified time limitations, an Israeli court may declare a foreign civil judgment enforceable if it finds that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment,
- the judgment is no longer appealable,
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy, and
- the judgment is executory in the state in which it was given.

Even if the above conditions are satisfied, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

An Israeli court also will not declare a foreign judgment enforceable if:

- the judgment was obtained by fraud,
- there was no due process,
- the judgment was rendered by a court not competent to render it according to the laws of private international law in Israel,
- the judgment is at variance with another judgment that was given in the same matter between the same parties and which is still valid, or
- at the time the action was brought in the foreign court a suit in the same matter and between the same parties was pending before a court or tribunal in Israel.

If a foreign judgment is enforced by an Israel court, it generally will be payable in Israeli currency. Judgment creditors must bear the risk of unfavorable exchange rates.

$150,000,000

Prospectus

, 2015

PART II

Information not Required in Prospectus

Item 8. Indemnification of Directors and Officers

Under the Israeli Companies Law, 5759-1999 (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.

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 under "Item 6—Directors, Senior Management and Employees—B. Compensation" in our Annual Report on Form 20-F for the fiscal year ended December 31, 2014, as filed with the SEC on March 31, 2015.

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, have entered into agreements with each of our office holders, that became effective immediately upon consummation of our initial public offering, which superseded and replaced 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 agree to indemnify our office holders for certain liabilities resulting from our initial public 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.

Item 9. Exhibits

Exhibit No.	**Description**
4.1	Form of Amended and Restated Articles of Association of Galmed Pharmaceuticals Ltd. (English Translation) (1)
4.2	Registration and Information Rights Agreement, dated December 2013, by and among Galmed Pharmaceuticals Ltd., Shirat HaChaim Ltd., David & Debora Goldfarb, Medgal S.A. and G. Yarom Medical Research Ltd. (2)
4.3	Galmed Pharmaceuticals Ltd. 2013 Incentive Share Option Plan (2)
5.1	Opinion of Tulchinsky, Stern, Marciano, Cohen, Levitski & Co.
23.1	Consent of Brightman Almagor Zohar & Co. (a Member of Deloitte Touche Tohmatsu Limited)
23.2	Consent of Tulchinsky, Stern, Marciano, Cohen, Levitski & Co. (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page) (filed herewith)

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(1) Incorporated herein by reference to Amendment No. 1 to the Registration Statement on Form F-1 filed with the SEC on February 28, 2014.

(2) Incorporated herein by reference to the Registration Statement on Form F-1 filed with the SEC on February 6, 2014.

Item 10. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement

provided, *however*, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1) (iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A. of Form 20-F at the start of any delayed offering or throughout a continuous offering provided, however, that a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Act or §210.3-19 if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of

providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any persons that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant and (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby further undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance under Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4), or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunder duly authorized, in the city of Tel Aviv, State of Israel, on March 31, 2015.

GALMED PHARMACEUTICALS LTD.

By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer

Power of Attorney and Signatures

Each person whose signature appears below hereby constitutes and appoints each of Allen Baharaff and Josh Blacher, acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities, to sign any or all amendments or supplements to this registration statement, whether pre-effective or post-effective and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done with respect to this registration statement or any amendments or supplements hereto or any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, in the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

SIGNATURE	**TITLE**	**DATE**
/s/ Chaim Hurvitz Chaim Hurvitz	Chairman of the Board, Class III Director; Chairperson of the R&D Committee	March 31, 2015
/s/ Allen Baharaff Allen Baharaff	President and Chief Executive Officer, Class II Director (Principal Executive Officer)	March 31, 2015
/s/ Josh Blacher Josh Blacher	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2015
/s/ Dr. Maya Halpern Dr. Maya Halpern	Chief Medical Officer, Class I Director	March 31, 2015
/s/ William Marth William Marth	Class III Director	March 31, 2015
/s/ Shmuel Nir Shmuel Nir	Class II Director	March 31, 2015
/s/ Tali Yaron-Eldar Tali Yaron-Eldar	Director; External Director; Chairperson of the Audit Committee; Chairperson of the Remuneration Committee	March 31, 2015
/s/ David Sidransky, M.D.		March 31, 2015

David Sidransky, M.D. Director; External Director

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