Galmed Pharmaceuticals Ltd.
Form 424B5
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Registration No. 333-203133

PROSPECTUS SUPPLEMENT

(To Prospectus dated July 1, 2015)

332,038 Ordinary Shares

We are offering 332,038 ordinary shares to certain existing investors under a securities purchase agreement dated August 3, 2017 entered into between us and the investors.

Our ordinary shares are traded on the NASDAQ Capital Market under the symbol “GLMD.” On August 2, 2017, the last reported sale price of our ordinary shares was $7.14 per share.

	Per Ordinary Share	**Total**
Public offering price	$ 7.10	$2,357,500
Proceeds, before expenses, to us	$ 7.10	$2,357,500

In a concurrent private placement, Chaim Hurvitz, our Chairman of the Board (through Shirat HaChaim Ltd., an entity controlled by Mr. Hurvitz, or Shirat HaChaim), and William Marth, a member of our Board, have agreed to purchase an aggregate of 49,295 ordinary shares at an offering price per share of $7.10. Closing of the private placement is expected to occur no later than September 15, 2017.

As of the date of this prospectus supplement, the aggregate market value of our outstanding ordinary shares held by non-affiliates was approximately $64.0 million, based on 12,267,860 ordinary shares outstanding, of which 7,790,012 ordinary shares were held by non-affiliates, and a per share price of $8.21 based on the closing sale price of our ordinary shares on July 26, 2017. We have sold securities with an aggregate market value of approximately $4.8 million pursuant to General Instruction I.B.5 of Form F-3 during the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement.

Investing in our ordinary shares involves a high degree of risk. Before making an investment decision, you should carefully consider all of the information set forth in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page S-5 of this prospectus supplement and under similar headings in the other documents that are incorporated by reference into this prospectus supplement.

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

We expect to deliver the ordinary shares in this offering on or about August 8, 2017.

The date of this prospectus supplement is August 3, 2017.

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Prospectus supplement

PROSPECTUS

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form F-3 (File No. 333-203133) that we initially filed with the Securities and Exchange Commission, or the SEC, on March 31, 2015, and that was declared effective by the SEC on July 1, 2015. This document is in two parts. The first part is this prospectus supplement which describes the terms of this offering of our ordinary shares and adds to and updates the information contained in the accompanying prospectus. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus, you should rely on the information in this prospectus supplement.

This prospectus supplement and the accompanying prospectus relate to the offering of our ordinary shares. Before buying any of the ordinary shares offered hereby, we urge you to read carefully this prospectus supplement and the accompanying prospectus, together with the information incorporated herein by reference as described below under the heading "Incorporation of Certain Documents by Reference." This prospectus supplement contains information about the ordinary shares offered hereby and may add to, update or change information in the accompanying prospectus.

You should rely only on the information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different or additional information.

We are not making offers to sell or solicitations to buy our ordinary shares in any jurisdiction in which an offer or solicitation is not authorized or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information in this prospectus supplement and the accompanying prospectus is accurate only as of the date on the front of the respective document and that any information that we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or the time of any sale of a security.

This prospectus supplement and the accompanying prospectus contain summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated herein by reference as exhibits to the registration statement, and you may obtain copies of those documents as described below under the section entitled "Where You Can Find More Information."

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus supplement and the accompanying prospectus contain and incorporate by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly-available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus supplement, accompanying prospectus or the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the headings “Risk Factors” in this prospectus supplement and the accompanying prospectus, and under similar headings in the other documents that are incorporated herein by reference. Accordingly, investors should not place undue reliance on this information.

The name of our product candidate, Aramchol™ (hereinafter referred to as “Aramchol”), is a registered trademark or trademark of Galmed Pharmaceuticals Ltd. in Israel, the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this prospectus supplement and the accompanying prospectus are the property of their respective owners. Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement and the accompanying prospectus to the “Company,” “Galmed,” “we,” “us,” “our” or similar references mean Galmed Pharmaceuticals Ltd., a corporation formed under the laws of the State of Israel, and its subsidiaries.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our ordinary shares. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information under the heading "Risk Factors" in this prospectus supplement on page S-5 and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

Our Company

We are a clinical-stage biopharmaceutical company focused on the development of Aramchol, a first in class, novel, once-daily, oral therapy for the treatment of Non-Alcoholic Steato-Hepatitis, or NASH for variable populations, as well as other liver associated disorders. We are currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol in 248 subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. Top line Data from the ARREST Study are expected to be available during the second quarter of 2018.

We also sponsor the ARRIVE Study, a proof-of-concept Phase IIa clinical trial designed to evaluate the safety and efficacy of Aramchol in up to 50 patients with HIV-associated NAFLD (Non-Alcoholic Fatty Liver Disease) and lipodystrophy. The ARRIVE Study is an investigator-initiated trial, conducted at the University of California San Diego by Professor Rohit Loomba. More information about the ARREST Study and the ARRIVE Study may be found on ClinicalTrials.gov identifiers: NCT02279524 and NCT02684591, respectively.

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, inducing beneficial modulation of intra-hepatic lipid metabolism. Aramchol's ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating down regulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol on fibrosis is mediated by down regulation of steatosis and directly on human collagen producing cells. We are investing efforts into better understanding the mechanisms by which Aramchol™ down regulates steatosis and fibrosis. Additional animal models are being investigated with variety of treatment regimens. The data, thus far, demonstrates dual mode of action of Aramchol on fibrosis via improvement of Fatty Acid oxidation as well a direct impact on stellate cells which are the collagen producing cells in the liver which results in reversing fibrosis. Aramchol has been granted by the FDA Fast Track designation status for the treatment of NASH.

Corporate Information

Galmed Pharmaceuticals Ltd. was incorporated in Israel on July 31, 2013 as a privately held company. However, our business has been operating since 2000 under a different group of companies established in the same year, or the Group. Originally, we operated under the parent company, Galmed Holdings Inc., 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, a company incorporated in Malta, or GIL (other than 0.1% of the share capital held by GHI). GIL held all of the equity rights in and to Galmed Medical Research Ltd., an Israeli company, or GMR, which became an inactive company in 2015. Our intellectual property was held by GIL. The research and development was conducted by GMR as a service to GIL on a cost plus basis. GIL was responsible for all product development.

On February 2, 2014, we underwent a reorganization, or the Reorganization, pursuant to which all of our 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 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 Galmed Research and Development Ltd., a newly formed Israeli company wholly owned by us. GIL held all of the equity rights in and to GMR, which became an inactive company in 2015. 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 a tax pre-ruling received from the Israeli Tax Authority, 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.

On March 18, 2014, we completed our initial public offering of 3,263,010 ordinary shares at a public offering price of $13.50 per share, which included 425,610 ordinary shares issued upon the exercise in full of the underwriters' option to purchase additional ordinary shares to cover over-allotments, for aggregate gross proceeds of approximately $44.1 million. Net of underwriting discounts, commissions and other estimated offering expenses, the offering raised approximately $39.7 million.

Our principal executive offices and registered office in Israel are located at 16 Tiomkin Street, Tel Aviv, Israel, 6578317 and our telephone number is +972-3-693-8448. Our Amended and Restated Articles of Association, or Articles, are on file in Israel with the office of the Israeli Registrar of Companies and available for public inspection at that office. 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 prospectus supplement. We have included our website address in this prospectus supplement solely as an inactive textual reference. The Company has duly designated Puglisi & Associates, with offices at 850 Library Avenue, Newark, Delaware 1971, as its authorized agent in the United States in connection with this offering.

Concurrent Private Placement

On August 3, 2017, we entered into a securities purchase agreement (the "Purchase Agreement") with Chaim Hurvitz, our Chairman of the Board (through Shirat HaChaim, a company incorporated under the laws of the State of Israel, of which Mr. Hurvitz is the controlling shareholder, president, chief executive officer and the chairman of its board of directors), and William Marth, a member of our Board, pursuant to which we will issue to Mr. Hurvitz (through Shirat HaChaim) and Mr. Marth an aggregate of 49,295 ordinary shares for a per share price of $7.10 in an offering exempt from registration under the Securities Act.

The closing of the investment under the Purchase Agreement, which is scheduled no later than September 15, 2017, is subject to certain conditions, including among others, that as of the closing date and as of the date of the Purchase Agreement, the representations and warranties of the Company shall be true and accurate in all material respects.

Prior to giving effect to the consummation of the offering contemplated by this prospectus supplement and the concurrent private placement, Mr. Hurvitz, beneficially owns approximately 8.3% of our ordinary shares as of the date of this prospectus supplement. After giving effect to the consummation of the offering contemplated by this prospectus supplement and the concurrent private placement (as if the same were to occur on the date of this prospectus supplement), Mr. Hurvitz would beneficially own approximately 8.3% of our ordinary shares.

Prior to giving effect to the consummation of the offering contemplated by this prospectus supplement and the concurrent private placement, Mr. Marth, beneficially owns approximately 0.3% of our ordinary shares as of the date of this prospectus supplement. After giving effect to the consummation of the offering contemplated by this prospectus supplement and the concurrent private placement (as if the same were to occur on the date of this prospectus supplement), Mr. Marth would beneficially own approximately 0.4% of our ordinary shares.

THE OFFERING

Ordinary shares offered by us	332,038 shares
Ordinary shares to be outstanding after this offering and the concurrent private placement	12,642,428 shares
Use of Proceeds	We currently intend to use the net proceeds from this offering and the concurrent private placement for (i) further clinical and pre-clinical development of existing and new programs, (ii) business development related activities and (iii) general corporate purposes. See “Use of Proceeds” on page S-9.
Risk Factors	Investing in our ordinary shares involves significant risks. See “Risk Factors” on page S-5, and under similar headings in other documents incorporated by reference into this prospectus supplement and the accompanying prospectus.
NASDAQ Capital Market symbol	GLMD

The above discussion is based on 12,261,095 ordinary shares outstanding as of July 31 2017, and excludes as of such date:

- 2,426,514 ordinary shares issuable upon exercise of outstanding stock options under our equity incentive plan, at a weighted average exercise price of $3.27;
- 42,965 outstanding restricted stock units, or RSUs; and
- 149,253 ordinary shares reserved for future awards under our equity incentive plan.

RISK FACTORS

An investment in our ordinary shares involves a high degree of risk. Prior to making a decision about investing in our ordinary shares, you should carefully consider the risks, uncertainties and assumptions discussed under Item 3D, "Risk Factors," in our Annual Report on Form 20-F for the fiscal year ended December 31, 2016, all of which are incorporated herein by reference and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future, together with information in this prospectus supplement and any other information incorporated by reference into this prospectus supplement, including the risk factors set forth below. See the sections of this prospectus supplement entitled "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference." Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. If any of these risks occur, our business, financial condition and operating results could be harmed, the trading price of our ordinary shares could decline and you could lose part or all of your investment.

This prospectus supplement also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements" for information relating to these forward-looking statements.

Risks Connected to our Securities, this Offering and the Concurrent Private Placement

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 oftentimes 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:

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

- termination of clinical trials;
- adverse events in our ongoing 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, management or other key personnel;
- legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;

- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of drugs we, our licensees or others develop;
- success of research and development projects;
- variations in our and our competitors' results of operations;
- changes in earnings estimates, cash flow guidance, or recommendations by securities 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.

Our President and Chief Executive Officer along with our Chairman of the Board, or our principal shareholders, currently beneficially own approximately 40% of our outstanding ordinary shares and after giving effect to the sale of ordinary shares in this offering and the concurrent private placement, our principal shareholders will beneficially own approximately 39% of our outstanding ordinary shares. Therefore, our principal shareholders will be able to exert significant control over matters submitted to our shareholders for approval.

Our principal shareholders currently beneficially own approximately 40% of our outstanding ordinary shares and after giving effect to the sale of ordinary shares in this offering and the concurrent private placement, our principal shareholders will beneficially own approximately 39% of our outstanding ordinary shares. As a result, these shareholders, if they acted together, could significantly influence 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.

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 supplement 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 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, our shareholders may not be able to collect any damages awarded by either a United States or foreign court.

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.

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 Israeli Companies Law, 5759-1999, as amended, 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.

Compliance with changing corporate governance and public disclosure regulations may result in additional expense.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and any new SEC regulations will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with potential evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from potential revenue-generating activities to compliance activities.

Management will have broad discretion as to the use of the net proceeds from this offering and the concurrent private placement, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and the concurrent private placement and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our products and cause the price of our ordinary shares to decline.

You will experience immediate and substantial dilution in the book value per ordinary share you purchase.

After giving effect to the sale of ordinary shares at the public offering price of $7.10 per share and the concurrent private placement at the public offering price, and after deducting estimated offering expenses, investors in this offering will experience immediate dilution of $6.40 per share, representing the difference between the public offering price per share and our as adjusted net tangible book value per share as of June 30, 2017. See “Dilution” for a more detailed discussion of the dilution you will incur if you purchase shares of common stock in this offering.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that may not be the same as the price per share in this offering or the concurrent private placement. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering or the concurrent private placement, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders, including investors who purchase ordinary shares in this offering or the concurrent private placement. The price per share at which we sell additional ordinary shares or securities convertible into ordinary shares in future transactions may be higher or lower than the price per share in this offering or the concurrent private placement.

Our shareholders may be diluted by the exercise of outstanding options to purchase ordinary shares or the vesting of our RSUs.

As of July 31, 2017, we have (i) 2,426,514 ordinary shares issuable upon the exercise of outstanding stock options, at exercise prices ranging from $0.01 to $9.73 (with a weighted average exercise price of $3.27 per share), and (ii) 42,965 issued and outstanding RSUs. You may incur dilution upon the grant of shares upon exercise of such outstanding options or upon the vesting of such RSUs.

A large number of shares may be sold in the market following this offering, which may depress the market price of our ordinary shares.

All of our ordinary shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act. As a result, a substantial number of our ordinary shares may be sold in the public market following this offering, which may cause the market price of our ordinary shares to decline. If there are more ordinary shares offered for sale than buyers are willing to purchase, then the market price of our ordinary shares may decline to a market price at which buyers are willing to purchase the offered ordinary shares and sellers remain willing to sell the shares.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and documents incorporated by reference into this prospectus supplement, the accompanying prospectus and the other documents we have filed with the SEC that are incorporated herein by reference may contain "forward-looking statements" within the meaning of the safe harbor provisions of Section 27A of the Securities Act, Section 21E of the Exchange Act, and the Private Securities Litigation Reform Act of 1995. 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," "target," "will," "project," "forecast," "continue" or their negatives or variations of thes 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:

- the timing and cost of our ongoing Phase IIB ARREST Study, and planned Phase III trials, for our product candidate, Aramchol for the treatment of patients who are overweight or obese and have pre diabetes or type II diabetes mellitus (hereinafter OD patients) with NASH, or whether Phase III trials will be conducted at all;

- completion and receiving favorable results of these Phase IIB ARREST Study and Phase III trials for Aramchol;

- regulatory action with respect to Aramchol by the U.S. Food and Drug Administration, or FDA, or the European Medicines Authority, or EMA, including but not limited to acceptance of an application for marketing authorization, review and approval of such application, and, if approved, the scope of the approved indication and labeling;

- the commercial launch and future sales of Aramchol or any other future products or product candidates;

- our ability to comply with all applicable post-market regulatory requirements for Aramchol in the countries in which we seek to market the product;

- our ability to achieve favorable pricing for Aramchol;

- our expectations regarding the commercial market for NASH in OD patients;

- third-party payor reimbursement for Aramchol;
- our estimates regarding anticipated capital requirements and our needs for additional financing;
- 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 our Annual Report on Form 20-F for the year ended December 31, 2016 filed with the SEC on March 23, 2017 in greater detail under the heading "Risk Factors" and elsewhere in this prospectus supplement. 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 report. 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.

You should read this prospectus supplement, the accompanying prospectus, the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

CAPITALIZATION AND INDEBTEDNESS

The table below sets forth our capitalization and indebtedness as of June 30, 2017:

- on an actual basis; and

- on a pro forma basis to reflect (i) the sale of an aggregate of 332,038 ordinary shares at the public offering price of $7.10 per share, for aggregate gross proceeds of approximately $2.29 million, and (ii) the sale of an aggregate of 49,295 ordinary shares in the concurrent private placement at a price per share of $7.10, for aggregate gross proceeds of approximately $340,000, in both cases after deducting estimated aggregate offering expenses payable by us.

As of June 30, 2017

	Actual	Pro Forma
	(in thousands, except share and per share data)	
Shareholders' equity:		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 12,219,186 shares as of June 30, 2017	$ 34	$ 35
Additional paid-in capital	$ 76,402	$ 79,060
Accumulated other comprehensive income (loss)	$ (20)	$ (20)
Accumulated deficit	$ (70,174)	$ (70,174)
Total shareholders' equity	$ 6,242	$ 8,901

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our ordinary shares offered hereby and from the concurrent private placement will be approximately $2.63 million, based on a public offering price of $7.10 per share, after deducting estimated offering expenses payable by us and assuming that we sell all of the shares offered hereunder and from the concurrent private placement.

We intend to use the net proceeds from the sale of the securities offered under this prospectus supplement and from the concurrent private placement for (i) further clinical and pre-clinical development of existing and new programs, (ii) business development related activities and (iii) general corporate purposes.

Although we have identified some potential uses of the net proceeds to be received upon completion of this offering and from the concurrent private placement, we cannot specify these uses with certainty. Our management will have broad discretion in the application of the net proceeds from this offering and from the concurrent private placement and could use them for purposes other than those contemplated at the time of this offering and from the concurrent private placement. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not result in our being profitable or increase our market value.

Until we use the net proceeds of this offering and from the concurrent private placement, we intend to deploy the funds in either (i) cash and cash equivalents or (ii) short-term, investment grade, interest-bearing instruments, consistent with our investment policy.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our Board 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. Our current plans are to retain future earnings primarily to finance the development of our business and for other corporate purposes.

DILUTION

If you invest in our ordinary shares, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our ordinary shares and the as adjusted net tangible book value per share of our ordinary shares after this offering and from the concurrent private placement.

The net tangible book value of our ordinary shares as of June 30, 2017 was approximately $6.2 million, or approximately $0.51 per share. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the total number of our ordinary shares outstanding.

After giving effect to the sale of 332,038 of ordinary shares in this offering at the public offering price of $7.10 per share and after giving effect to the sale by us of 49,295 ordinary shares in the concurrent private placement at a price of $7.10 per share and the receipt of an estimated $2.63 million of net proceeds therefrom, after deducting estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2017 would have been approximately $8.9 million, or approximately $0.70 per share. This represents an immediate increase in net tangible book value of approximately $0.19 per share to our existing shareholders and an immediate dilution in as adjusted net tangible book value of approximately $6.40 per share to investors participating in this offering, as illustrated by the following table:

Offering price per share of ordinary shares		$7.10
Net tangible book value per share as of June 30, 2017	$0.51	
Increase in net tangible book value per share after this offering and the concurrent private placement	$0.19	
As adjusted net tangible book value per share as of June 30, 2017, after giving effect to this offering and the concurrent private placement		$0.70
Dilution per share to investors participating in this offering		$6.40

The table above assumes for illustrative purposes that an aggregate of 332,038 ordinary shares are sold in this offering at a price of $7.10 per share, for aggregate gross proceeds of approximately $2.36 million, and that an aggregate of 49,295 ordinary shares are sold in the concurrent private placement at a price of $7.10 per share, for aggregate gross proceeds of approximately $350,000

The above discussion and table are based on 12,219,186 ordinary shares outstanding as of June 30, 2017, and excludes as of such date:

- 2,406,315 ordinary shares issuable upon exercise of outstanding stock options under our equity incentive plan, at a weighted average exercise price of $3.27;
- 44,685 outstanding RSUs; and
- 204,253 ordinary shares reserved for future awards under our equity incentive plan.

To the extent that any of these outstanding options are exercised or that outstanding RSUs vest or we issue additional shares under our equity incentive plans, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

MARKET FOR OUR ORDINARY SHARES

Our ordinary shares have been listed on the Nasdaq Capital Market under the symbol “GLMD” since March 13, 2014. Prior to that date, there was no public trading market for our ordinary shares. Our initial public offering was priced at $13.50 per share. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on the NASDAQ Capital Market:

Annual Information:	**Low**	**High**
2014	$4.58	$18.73
2015	$5.54	$13.50
2016	$2.78	$7.91
Quarterly Information		
First Quarter 2015	$5.54	$13.50
Second Quarter 2015	$8.10	$11.86
Third Quarter 2015	$7.00	$10.94
Fourth Quarter 2015	$7.06	$10.20
First Quarter 2016	$3.50	$7.91
Second Quarter 2016	$3.88	$7.72
Third Quarter 2016	$3.53	$5.77
Fourth Quarter 2016	$2.78	$4.74
First Quarter 2017	$3.43	$5.79
Second Quarter 2017	$4.40	$7.09
Third Quarter 2017 (ending August 2, 2017)	$6.20	$8.60
Monthly Information:		
February 2017	$3.90	$5.24
March 2017	$4.30	$5.79
April 2017	$4.55	$5.49
May 2017	$4.40	$5.78
June 2017	$4.69	$7.09
July 2017	$6.20	$8.60
August 2017 (ending August 2, 2017)	$ 6.74	$ 7.21

PLAN OF DISTRIBUTION

We have arranged for the sale of the shares we are offering pursuant to this prospectus supplement to one or more investors through a securities purchase agreement directly between the purchasers and us. All of the shares will be sold at the same price and, we expect, at a single closing. We established the price following negotiations with prospective investors and with reference to the prevailing market price of our common stock, recent trends in such

price and other factors. It is possible that not all of the shares we are offering pursuant to this prospectus supplement will be sold at the closing, in which case our net proceeds would be reduced. We expect that the sale of the shares will be completed on or around the date indicated on the cover page of this prospectus supplement.

LEGAL MATTERS

Certain legal matters with respect to U.S. law will be passed upon for us by McDermott Will & Emery LLP, New York, New York, and certain legal matters with respect to Israeli law will be passed upon for us by Meitar Liquornik Geva Leshem Tal, Ramat Gan, Israel.

EXPERTS

The consolidated financial statements of the Company for the year ended December 31, 2016 incorporated in this prospectus supplement by reference have been audited by the accounting firm of Brightman Almagor Zohar & Co. (a member of Deloitte Touche Tohmatsu Limited), an independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form F-3 (File No. 333-203133) with the SEC for the ordinary shares offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus, including the information incorporated by reference herein and therein, do not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The SEC's Internet site can be found at *http://www.sec.gov*. In addition, we make available on or through our Internet site copies of these reports as soon as reasonably practicable after we electronically file or furnish them to the SEC. Our Internet site can be found at http://galmedpharma.investorroom.com/sec-filings. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into this prospectus supplement.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus supplement certain information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Any information that we file with the SEC after the date of this prospectus supplement will automatically update this prospectus supplement, until the filing of a post-effective amendment to this prospectus which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold. We incorporate by reference into this prospectus supplement the documents listed below, which are considered to be a part of this prospectus supplement:

- Annual Report on Form 20-F for the fiscal year ended December 31, 2016, filed on March 23, 2017, as amended on June 23, 2017;
- Current Reports on Forms 6-K furnished on March 23, 2017, April 5, 2017, April 27, 2017, May 15, 2017, June 8, 2017, June 8, 2017, and July 31, 2017; and
- the description of our ordinary shares contained in our Form 8-A12B filed on March 11, 2014, including any reports filed for the purpose of updating such description.

We will provide, upon written or oral request, to each person to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of these filings, at no cost, by writing us at Galmed Pharmaceuticals Ltd., 16 Tiomkin Street, Tel Aviv, Israel, 6578317. Our telephone number is +972-3-693-8448.

ENFORCEABILITY OF CIVIL LIABILITIES

We are organized under the laws of the State of Israel, and many of our directors and executive officers, as well as the Israeli experts named herein are not residents of the United States, and substantially all of their assets and our assets are located outside the United States. Service of process upon our non-U.S. resident directors and executive officers or the Israeli experts named herein and enforcement of judgments obtained in the United States against us, our directors and executive officers, or the Israeli experts named herein, may be difficult to obtain within the United States. For further information regarding enforceability of civil liabilities against us and certain other persons, see the risk factor "*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 supplement 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.*" under the heading "Risk Factors" herein.

Puglisi & Associates is the U.S. agent authorized to receive service of process in any action against us arising out of this offering. The address of Puglisi & Associates is 850 Library Avenue, Newark, Delaware 19711.

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 July 1, 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