Galmed Pharmaceuticals Ltd.
Form 20-F
March 13, 2019

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 20-F

..**REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

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

For the fiscal year ended December 31, 2018

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

OR

..**SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission File No. 001-36345

GALMED PHARMACEUTICALS Ltd.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of the Registrant's name into English)

State of Israel

(Jurisdiction of incorporation or organization)

16 Tiomkin Street, Tel Aviv, Israel 6578317

(Address of principal executive offices)

Allen Baharaff

President and Chief Executive Officer

16 Tiomkin Street

Tel Aviv, Israel 6578317

E-mail: ab@galmedpharma.com
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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	*Name of each exchange on which registered*
Ordinary shares, par value NIS 0.01 per share	**Nasdaq Capital Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

Title of each class
N/A

Securities registered or to be registered pursuant to Section 15(d) of the Act.

Title of each class
N/A

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report (December 31, 2018): 21,018,919 ordinary shares are outstanding

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ **No** x

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ¨ **No** x

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such a shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x **No** ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x **No** ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ **Accelerated filer** x **Non-accelerated filer** ¨
Emerging growth company x

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. x

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP x **International Financial Reporting Standards as issued by the International Accounting Standards Board** ¨ **Other** ¨

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the Registrant has elected to follow: Item 17 ¨ **Item 18** ¨

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ **No** x

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ¨ **No** ¨

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ABOUT THIS ANNUAL REPORT

All references to “we,” “us,” “our,” “the Company” and “our Company”, in this Annual Report on Form 20-F, or our annual report, are to Galmed Pharmaceuticals Ltd. and its subsidiaries, unless the context otherwise requires. All references to “shares” or “ordinary shares” are to our ordinary shares, NIS 0.01 nominal par value per share. All references to “Israel” are to the State of Israel. “U.S. GAAP” means the generally accepted accounting principles of the United States. Unless otherwise stated, all of our financial information presented in this annual report has been prepared in accordance with U.S. GAAP. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding. Unless otherwise indicated, or the context otherwise requires, references in this annual report to financial and operational data for a particular year refer to the fiscal year of our company ended December 31 of that year.

Our reporting currency and financial currency is the U.S. dollar. In this annual report, “NIS” means New Israeli Shekel, and “$,” “US$” and “U.S. dollars” mean United States dollars.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as “believe,” “expect,” “intend,” “plan,” “may,” “should,” “anticipate,” “could,” “might,” “seek,” “target,” “will,” “projec “continue” or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements may be included in, among other things, various filings made by us with the U.S. Securities and Exchange Commission, or 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 planned pivotal Phase 3/4 ARMOR trial, or the ARMOR Study, for our product candidate, Aramchol, or whether a pivotal trial will be conducted at all;

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completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial;

- regulatory action with respect to Aramchol by the U.S. Food and Drug Administration, or the 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 and any future 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 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 this annual report in greater detail under the heading "Risk Factors" and elsewhere in this annual report. 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 annual 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.

EXPLANATORY NOTE

Market data and certain industry data and forecasts used throughout this annual report were obtained from internal company surveys, market research, consultant surveys commissioned by the Company, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys commissioned by the Company and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. However, this information may prove to be inaccurate because of the method by which some of the data for the estimates is obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. As a result, the market and industry data and forecasts included or incorporated by reference in this annual report, and estimates and beliefs based on that data, may not be reliable. We have relied on certain data from third-party sources, including internal surveys, industry forecasts and market research, which we believe to be reliable based on our management's knowledge of the industry. However, we have not ascertained the underlying economic assumptions relied upon therein. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not necessarily know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements as to our market position are based to the best of our knowledge on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this annual report, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" in this annual report.

PART I

ITEM 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

ITEM 2. Offer Statistics and Expected Timetable.

Not applicable.

ITEM 3. Key Information.

A. Selected Financial Data.

The following table sets forth our selected consolidated financial data for the periods ended and as of the dates indicated, which reflects the financial data of the Company and the financial data of Galmed Holdings Inc., a holdings company incorporated in the British Virgin Islands, or GHI, our predecessor, prior to the Reorganization (as described below). The following selected consolidated financial data for our Company should be read in conjunction with the financial information, "Item 5. Operating and Financial Review and Prospects" and other information provided elsewhere in this annual report and our consolidated financial statements and related notes. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and is qualified in its entirety thereby. In the opinion of our management, our unaudited consolidated financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of our financial position, results of operations and cash flows as of and for the periods indicated therein.

The selected consolidated statement of operations data for the years ended December 31, 2016, 2017 and 2018, and the selected consolidated balance sheet data as of December 31, 2017 and 2018, have been derived from our audited consolidated financial statements set forth elsewhere in this annual report. The selected consolidated statement of operations data for the years ended December 31, 2014 and 2015, and the selected consolidated balance sheet data as of December 31, 2014, 2015 and 2016, have been derived from our audited consolidated financial statements not included in this annual report.

Consolidated Statement of Operations Data

	Year ended December 31,				
	2014	2015	2016	2017	2018
	(in thousands)				
Revenue	-	-	$467	$1,085	$2,038
Research and development expenses	6,664	7,629	14,271	9,650	8,313
General and administrative expenses	2,478	3,246	3,078	3,799	4,440
Operating loss	9,142	10,875	16,882	12,364	10,715
Financial expenses	10	180	372	232	42
Financial Income	(50)	(433)	(407)	(297)	(976)
Taxes on income	1	—	106	—	75
Net loss	$9,103	$10,622	$16,953	$12,299	$9,856
Comprehensive loss	9,099	10,832	16,832	12,221	9,860
Diluted net loss per ordinary	$0.88 (*)	$0.96	$1.49	$0.98	$0.54
Weighted number of ordinary shares used in computing loss per ordinary shares	10,323,686 (*)	11,101,453	11,374,653	12,487,349	18,137,689

(*) Retroactively adjusted to reflect the 729:1 share split, which occurred upon the consummation of the Reorganization (as defined below).

Consolidated Balance Sheet data:

	As of December 31,				
	2014	2015	2016	2017	2018
	(In thousands)				
Cash and cash equivalents	$23,736	$4,156	$3,097	$13,021	$24,159
Short-term deposits and marketable securities	8,250	18,845	12,351	5,976	66,029
Other receivables	165	379	284	155	218
Fixed assets	774	883	718	491	194
Total assets	32,925	24,263	16,450	19,643	90,600
Total liabilities	1,518	2,718	5,375	3,848	2,706
Total shareholders' equity	31,407	21,545	11,075	15,795	87,894
Number of ordinary shares issued and outstanding	11,100,453	11,100,453	12,149,226	14,435,161	21,018,919

B. Capitalization and Indebtedness.

Not applicable.

C. Reasons for the Offer and Use of Proceeds.

Not applicable.

D. 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 significant additional losses in the future and may never be profitable.

We are a clinical-stage biopharmaceutical company with an operating history limited to pre-clinical and clinical drug development and no approved products. To date, we have focused nearly exclusively on developing our product candidate, Aramchol. 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 have funded our research and development programs and operations to date primarily through proceeds from private placements and public offerings. 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, although we have generated revenue from our licensing agreement with Samil Pharm. Co., Ltd., or Samil. 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, 2016, 2017, and 2018 was approximately $17.0 million, $12.3 million, and $9.9 million, respectively. As of December 31, 2018, we had an accumulated deficit of $86.5 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, excluding the licensing revenue we recorded in connection with that certain Samil Agreement (as defined below), as our 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 from sales of Aramchol and any future product candidates, if any. We do not expect to generate revenue other than subsequent royalties and/or milestones that can be earned in connection with the Samil Agreement or other potential license agreements, unless and until we, or an ultimate third-party licensor or acquirer, obtain regulatory and marketing approval of, and commercialize, Aramchol, and any future product candidates. We will continue to incur significant research and development and general and administrative expenses related to our operations. We expect to continue to incur losses for the foreseeable future, which may be significant, and these losses will likely increase as we:

- initiate and manage our planned ARMOR Study and any additional clinical trials for Aramchol and any future product candidates and initiate additional research and development programs;
- seek regulatory approvals for Aramchol and any 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 Aramchol and any future product candidates receives applicable regulatory approval and we opt to commercialize it ourselves;
- seek to in-license additional products or technologies to develop;
- hire additional management and other personnel; and
- move towards commercialization of Aramchol, and any future product candidates, if any.

We may out-license Aramchol, including through a territorial license, a worldwide license, or a license for a particular indication, before it is approved by any applicable regulatory agency, commercialized and/or generates revenue, depending on a number of factors, including, but not limited to, our ability to:

- demonstrate a compelling and/or novel, pre-clinical, unique mechanism of action of Aramchol;
- obtain adequate clinical results from and progress from the clinical development of Aramchol;
- develop and obtain regulatory approvals in the countries and for the uses we intend to pursue for Aramchol;

- contract for the manufacture of commercial quantities of Aramchol by a current good manufacturing practice, or cGMP, compliant manufacturing facility 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 for 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 significantly increase in connection with our planned ARMOR Study and initiation of any other pre-clinical or clinical trials. In addition, if we obtain marketing approval for Aramchol and opt to commercialize it ourselves, we will likely initially incur significant expenses associated with outsourcing sales, marketing and manufacturing functions to 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 pre-clinical and 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 Aramchol, and any future product candidates, obtain regulatory approvals or achieve market acceptance or favorable pricing for Aramchol and any future product candidates.

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 Aramchol's and any future product candidates development efforts, obtain regulatory approval for Aramchol and any future 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 for these products will depend on a number of factors, including:

- the timing and scope of regulatory approvals in the countries we intend to pursue with respect to the commercialization of Aramchol and any future product candidates, including the indications for which they are approved;
- the competitive environment;
- the ability for Aramchol and future product candidates to be manufactured, whether by us or third parties, in compliance with applicable regulatory requirements, including cGMP;
- our ability to effectively promote Aramchol and any future product candidates, whether directly or using third parties, consistent with the approved indications and labeling in the countries in which we intend to pursue approval;
- the acceptance by the medical community of the safety and clinical efficacy of Aramchol and any future product candidates and their potential advantages over other therapeutic products;

- the development of a non-invasive method for diagnosing NASH as an alternative to the current gold standard of liver biopsy, which we view as a rate-limiting factor to complete market uptake because of its expense and its risks and discomfort to patients;

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

As of December 31, 2018, we had a net working capital of $87.7 million, cash and cash equivalents of $24.2 million, short-term deposits of $6.1 million and marketable debt securities of $60.0 million. Based on our current operating plan, we currently estimate that our cash position will support our current clinical trials and operations as currently conducted for more than 12 months from the date of issuance of this annual report. We will need to raise substantial, additional capital to fund our operations and to develop Aramchol for, and beyond its current development stage for the NASH indication, as well as additional indications, and ultimately commercialize it, if we opt to do so ourselves, for NASH or any other indication. In addition, we may choose to expand our current research and development focus, or other clinical operations as well as the development of other molecules and/or combination of Aramchol with other molecules for NASH or other liver and inflammatory diseases as well as non-invasive biomarkers, which may also require additional capital. Our future capital requirements may be substantial and will depend on many factors including:

- acceptance of our planned Investigational New Drug application, or IND, or foreign equivalent for the ARMOR Study by the FDA and any other foreign regulatory authority;
- adhering to patient recruitment in our clinical trials and sponsored trials;
- our clinical trials and sponsored trials results;
- developing Aramchol and combination of it for the treatment of other conditions or indications beyond NASH, 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, and choose to commercialize Aramchol ourselves, including the cost and timing of establishing external, and potentially in the future, internal, sales and marketing capabilities to market and sell Aramchol;

- the costs associated with any product liability or other lawsuits related to Aramchol and any future product candidates, if any;

- the costs associated with post-market compliance with regulatory requirements, and of addressing any allegations of non-compliance by regulatory authorities in countries where we plan to market and sell Aramchol and any future product candidates;

- the demand for Aramchol and any future product candidates;

- 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.

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 Aramchol and any future 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, potentially substantially.

Any debt, equity or structured financing that we may need or desire 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 capital structure, financial condition and results of operations.

Any additional capital raised through the sale of equity or equity-linked securities will dilute our current shareholders' ownership in us, potentially substantially, and could also result in a decrease in the market price of our ordinary shares. The terms and conditions 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 Aramchol. If we fail to obtain necessary funds for our operations, we will be unable to develop and commercialize Aramchol and any future product candidates.

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 existing and future clinical trials and pre-clinical studies;
- the regulatory path of Aramchol and any future product candidates;
- the results of our clinical trials, which are unpredictable in product candidate development;
- our ability to successfully commercialize Aramchol and any future 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 Aramchol and any future product candidates and addressing regulatory and other issues that may arise post-approval;

- the breadth of the labeling, assuming that Aramchol and any future product candidates are 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 candidates;

- 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;

- the costs associated with contracting with third parties to manufacture the product and to perform other necessary services;

- 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 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 the 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 which was subsequently liquidated in February 2019. In connection with the Reorganization, we obtained a tax pre-ruling, or 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 Section 104 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. See also "Item 4. Information on the Company—Historical Background and Corporate Structure" below.

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 (clinical and pre-clinical) of our product candidate, Aramchol. We recently completed our Phase 2b ARREST Study, or the ARREST Study and are planning to initiate the ARMOR Study of Aramchol in 2019. As a result, our business is largely dependent on the commencement of and success of the ARMOR Study and our ability to complete the development of, obtain regulatory approval for and successfully commercialize Aramchol in a timely manner. The commencement of the ARMOR Study is dependent, in part, upon the success of our end of Phase 2b meeting that we plan to hold with the FDA during March 2019 and agreement on an IND for the ARMOR Study that, dependent on the outcome of that meeting, we plan to file with the FDA. There can be no assurance regarding the outcome of the planned end of Phase 2b meeting with the FDA or the IND. The process to develop, obtain regulatory approval for and commercialize Aramchol is long, complex, costly and uncertain as to its outcome.

The research, development, testing, clinical trials, 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 have not received marketing approval for Aramchol in any 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 authorization 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. The results of clinical trials may be unsatisfactory, and even if we believe those clinical trials to be successful, the FDA, or other regulatory authorities, may not grant marketing authorization should we be in a position to request it.

The requirements and length of time for approval vary in different jurisdictions and could involve additional studies of Aramchol beyond those we currently anticipate, including potentially post-approval studies. The time required to obtain approval in other countries might differ from that required to obtain FDA approval in the United States. The marketing approval process in other countries may include all of the risks detailed above regarding FDA approval as well as other risks. In particular, in many countries outside the United States, it is required that a product receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. In other countries, product approval depends on showing superiority to an approved therapy. This can result in significant expense to conduct 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 Aramchol and any future product candidates 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.

Commencement of our ARMOR Study is subject to the success of our planned end of Phase 2b meeting with the FDA and acceptance of our planned IND or foreign equivalent by the FDA and other regulatory authorities and even if commenced and completed, the outcome is inherently uncertain.

We are planning to have an end of Phase 2b meeting with the FDA in March 2019 and depending on the outcome of that meeting, we plan to file an IND with the FDA as well as well as foreign equivalents with other regulatory authorities for our planned ARMOR Study. Commencing this clinical trial, and any other clinical trials we may initiate, is subject to acceptance by the FDA of an IND and acceptance by other regulatory authorities of the foreign equivalent of an IND, and finalizing the planned trial design based on discussions with the FDA and other applicable regulatory authorities. In the event that the FDA or any other regulatory authority requires us to complete additional preclinical studies or we are required to satisfy other FDA or other regulatory requests, the start of the ARMOR Study or any of our other programs may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trial or change their position on the acceptability of our planned trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. In addition, while we have designed our planned clinical trial protocol for the ARMOR Study taking into consideration the most recent FDA guidance, it still remains unclear whether the FDA will agree with a number of aspects of our planned clinical trial design including the (i) duration of study, (ii) number of subjects required, (iii) dosages, and (iv) approvable endpoints. These factors, among others, would play a material role in determining the cost of the ARMOR Study and ultimate probability of success. As a result of the foregoing, the research and development, preclinical studies and clinical testing of any product candidate is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process.

We may be forced to abandon development of Aramchol, or any future product candidates, which would have a material adverse effect on our business and may force us to cease operations.

Upon the completion of any clinical or pre-clinical trial and/or tests, the results might not support the desired indications for use. Further, success in earlier clinical trials do 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 or pre-clinical testing. The clinical trial process may fail to demonstrate that Aramchol is safe and/or effective for the indications we seek. Any such failure may cause us to abandon Aramchol and may delay development of other potential product candidates. Any delay in, or termination or suspension of, our clinical trials may delay the requisite filings with the FDA or other regulatory agencies and, ultimately, our ability to commercialize Aramchol and any future product candidates and generate product revenues. We are currently preparing to commence the ARMOR Study. If the ARMOR Study is commenced and the results of the ARMOR Study are not successful, then the completion of development of Aramchol or any future product candidate may be significantly delayed or abandoned which would have material adverse effect on our business, liquidity, operating results and financial condition and may force us to cease operations.

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

We may acquire or 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 pre-clinical 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 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 complete or commence 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 authorities 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 assurance or guarantee that the trials will be successful. On the contrary, most candidate drugs that begin 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 successfully complete one phase of clinical trials 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 permitted to proceed. 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 authorization to commence a clinical trial or complying with regulatory requirements for clinical trials or with the 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 designate Aramchol as a Breakthrough Therapy, a designation that could, among other benefits, expedite the conduct of clinical trials;

- 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; and

- inadequate funding.

If commenced, the ARMOR Study may also be terminated as a result of, but not limited to, safety signals. In addition, the ARMOR Study or other clinical trials may be suspended or terminated by us, the FDA or other regulatory authorities, the principal investigator at a site, the IRBs at the sites where such boards are overseeing a trial or the data safety monitoring board, or the 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, in particular good clinical practice requirements, or GCP, or the FDA-authorized clinical protocols;

- negative findings upon inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;

- safety issues or lack of clinical drug activity or effectiveness; and

- lack of adequate funding to continue the clinical trials.

To date, we have already experienced material delays in the ARREST Study largely related to significantly slower than expected recruitment and the length of time required to obtain regulatory authorizations to proceed with clinical trials, as well as the termination of a Phase 2a trial of Aramchol for the treatment and dissolution of cholesterol gallstones. We may experience further delays in any or all of our clinical trials, and there can be no assurance that we will not experience such risks in the future as we progress with our planned clinical trials.

Furthermore, positive results in previous clinical studies of Aramchol may not be predictive of similar results in future clinical trials. Also, interim results, if at all, 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- and mid-stage development. Accordingly, the results from the completed pre-clinical 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 and/or pre-clinical trials, or to even terminate the development program entirely. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical and clinical studies 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.

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, if ever commercialized.

Liver biopsy is the standard approach for the diagnosis of inflammation and fibrosis associated with NASH. However, the procedure-related morbidity and, in rare cases, mortality, sample errors, costs, patient discomfort and thus lack of patient interest in undergoing the procedure 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 generally sent for liver biopsy. Because NASH tends to be asymptomatic until the disease progresses, many individuals with NASH remain undiagnosed until the disease has reached its late stages, if at all. 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 patients that take Aramchol, when and if it approved, 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.

While we, and other companies in the industry are currently working on advancing non-invasive diagnostic approaches, none of these has been clinically validated, and the timetable for commercial validation, if at all, is uncertain. Moreover, such diagnostics may also be subject to regulation by FDA or other regulatory authorities as medical devices and may require premarket clearance or approval.

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 Aramchol is both safe and effective for its intended use or uses, obtaining approval of an NDA, or other regulatory approval, 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 treatment of NASH in patients;
- 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 pre-clinical 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 pre-clinical studies or clinical trials;

- the applicable regulatory agencies may not accept data generated at our clinical trial sites;

- the data collected from pre-clinical 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 pre-clinical 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, or REMS, 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 4 clinical trials, in connection with Aramchol.

Before we can submit an NDA to the FDA or a similar approval application to other regulatory authorities, as applicable, we (or our commercialization partner, as the case may be) must conduct one or more clinical trials that will be substantially broader than our ARREST study. We will also need to agree on a protocol with the FDA, EMA or any other regulatory authorities for any clinical trial(s) before commencing any such trial. Clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, the results of the ARREST Study or any future clinical trials that we may conduct may or may not be successful. The applicable regulatory agencies may suspend all clinical trials or require that we conduct additional clinical, pre-clinical, 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 indications for use 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 or have other properties that could delay or prevent its regulatory approval or result in significant negative consequences following marketing approval, if any, which could substantially increase commercialization costs or even force us to cease operations.

Undesirable side effects caused by Aramchol could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or applicable foreign regulatory authorities. To date, we have completed six clinical trials of Aramchol, one proof of concept study in patient with gallstones, and a Phase 2a, investigator initiated clinical trial.

In our Phase 1A clinical trial, we enrolled 17 healthy volunteers. A total of 45 adverse events were reported in 13 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 1B placebo-controlled clinical trial with 25 healthy and mildly overweight male volunteers a total of 68 adverse events were reported by 80% of the subjects (placebo 89%; Aramchol 30mg 67%; Aramchol 300 mg 86%). 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 determined to be unrelated to Aramchol and all of the adverse events were transient and gave no indication of target organ toxicity. 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 2a placebo-controlled trial with 60 subjects with steatosis due to NAFLD or NASH, a similar proportion of patients from each treatment group reported adverse events (placebo 55%; Aramchol 100mg 40%, Aramchol 300mg 45%). Most adverse events were mild and transient. None of the adverse events reported in the Aramchol groups were considered related to the investigational drug. Three adverse events were initially considered to be related to the study drug; however, after un-blinding it turned out that they occurred in the placebo group. In addition, one serious adverse events (acute appendicitis) was reported in the placebo group. There were no deaths or other significant adverse events reported in this study.

In 2016, we performed a PK study involving 66 Chinese subjects, or the Chinese PK Study, who are domiciled in the United States, consisting of two parts. Overall treatment with Aramchol 400 mg and 600 mg was well tolerated, all adverse events were mild, and no safety signal was identified. No serious adverse events or deaths were reported. We deemed no changes were required in the enrollment of Chinese patients into the ARREST Study

An additional Phase 2a, proof of concept study in patients with gallstones was halted due to poor patient recruitment and change in company focus. The primary end-point was to prove that Aramchol dissolves newly formed gallbladder gallstones following bariatric surgery. Patients were to be assigned to one of three treatment arms; 400mg tablets, 600mg tablets and placebo. Only 9 patients were enrolled, and seven patients completed the study (before it was halted). A similar proportion of subjects from each treatment group reported events; seven in the placebo group, nine in the 400 mg Aramchol group, and five in the 600 mg Aramchol group. One subject experienced two events of severe cholecystitis in the Aramchol 600 mg group which were considered a serious adverse event and led to investigational product discontinuation. It should be noted that to be included in this study the subject must have had a history of gall bladder disease and gallstones, therefore the subject’s medical history is an important confounding factor.

In the investigator initiated Phase 2a proof-of-concept ARRIVE study that evaluated the safety and efficacy of Aramchol at 600mg/day versus placebo in 50 patients with HIV-associated lipodystrophy and NAFLD, no serious adverse events related to Aramchol were observed.

In the recently completed ARREST Study that enrolled 247 NASH patients with biopsy-proven NASH who were overweight or obese and had pre-diabetes or type II diabetes mellitus, serious adverse events were reported in 12.5%, 8.9% and 9.2% of patients in placebo, Aramchol 400mg and 600mg arms, respectively. No clustering of event type or atypical events for the studied population were reported in either Aramchol arms. Early terminations due to adverse

events occurred in 4.2%, 3.0% and 4.1% in placebo, Aramchol 400mg and 600mg arms, respectively. Most frequent adverse events included headaches, UTI, pruritus, nausea, influenza, constipation and fatigue.

In 2019, we completed a PK study involving 16 healthy subjects to assess whether dose splitting of Aramchol 600mg to twice daily 300mg will significantly increase plasma levels. The treatment in both dosing regimens was similar in terms of safety and was well tolerated.

Although we have not seen any evidence of these reactions causing a safety concern in our completed clinical trials, it is possible that the FDA may ask for additional data regarding any adverse events seen in our trials. Results of our future trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or applicable foreign regulatory authorities could order us to cease further development of or deny approval for Aramchol for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete future trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Even if Aramchol receives marketing approval, we or others may later identify undesirable side effects caused by the product. In such an event, regulatory authorities may:

- suspend or withdraw their approval of the product;
- require the addition of labeling statements, such as warnings, so-called “black box warnings,” contraindications or restrictions on the product’s intended use;
- require us to issue specific communications to healthcare professionals, such as “Dear Doctor” letters;

- issue negative publicity regarding the affected product, including safety communications;

- impose a risk evaluation and mitigation strategy (REMS), in the case of FDA, or similar risk management strategies in the case of foreign regulators;

In addition to these potentially significant negative consequences, we could be required to change the way the product is administered, conduct additional pre-clinical studies or clinical trials or restrict or cease the distribution or use of the product, and/or be sued and held liable for harm caused to patients. The foregoing or other 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.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, patient willingness to undergo a liver biopsy in our NASH trials, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and disadvantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Potential patients for Aramchol may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our studies.

We will be required to identify and enroll a sufficient number of patients in the U.S. with NASH for each of our planned clinical trials of Aramchol in this indication. We also may encounter difficulties in identifying and enrolling U.S. NASH patients who meet the eligibility criteria for our planned clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other foreign regulatory agencies. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays, additional expenses, or may require us to abandon one or more clinical trials.

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 or guidance or unanticipated events during our clinical trials may result in the need for us to amend clinical trial protocols. Amendments may require review and approval by regulators and/or IRBs, and re-consent subjects, 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.

Even if Aramchol, or any future product candidates that we may develop, receives marketing approval, we will continue to face extensive regulatory oversight and 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 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 Aramchol and any future product candidates, 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, Aramchol and any future product candidate's development costs will increase and our ability to out-license Aramchol and any future product candidates may be impeded.

If we obtain approval to commercialize Aramchol outside of the United States or out-license Aramchol to additional territories outside 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 or we out-license Aramchol to additional territories 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, or potentially any future product candidates 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, warnings or contraindications 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 REMS;

- availability of alternative treatments, including, any 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 inconsistent with the FDA-approved indications and other conditions or restrictions contained in the approved labeling, including the prescribing information, for the product. 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 labeling, which is commonly known as "off label" use. If we are found to have promoted Aramchol or any future product candidates for such "off label" uses, we may become subject to significant liability under a variety of statutory theories typically alleged by U.S. regulatory authorities. In particular, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion, has enjoined several companies from engaging in off-label promotion, and has requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

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 Aramchol and any future product

candidates and how much or under what circumstances healthcare providers will prescribe or administer Aramchol and any future product candidates.

In both the United States and other countries, sales of Aramchol and any future product candidates 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 the 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 the 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, 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 Barack 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 the 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.

There have been judicial and congressional challenges to the Affordable Care Act, as well as efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the ACA. However, to date, the Executive Orders have had limited effect and the Congressional activities have not resulted in the passage of a law repealing or replacing the ACA. If a law is enacted, many if not all of the provisions of the PPACA may no longer apply to prescription drugs. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future products are paid for and reimbursed by government and private payers our business could be adversely impacted. On December 14, 2018, a federal district court in Texas ruled that the PPACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the PPACA. The case, Texas, et al, v. United States of America, et al., (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge. We are not able to state with any certainty what will be impact of this court decision on our business pending further court action and possible appeals.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. 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 or any future product candidates, these 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 or any future product candidates 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, 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.

Various states, such as California, have also taken steps to consider and enact laws or regulations that are intended to increase the visibility of the pricing of pharmaceutical products with the goal of reducing the prices at which pharmaceutical products are sold. Because these various actual and proposed legislative changes are intended to operate on a state-by-state level rather than a national one, we cannot predict what the full effect of these legislative activities may be on our business in the future.

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, Aramchol or any future product candidates, 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 Aramchol or any future product candidates. 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 any future 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 that may affect reimbursement, the 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, of 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 Aramchol and any future product candidates to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for Aramchol and any future product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Aramchol and any future product candidates. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize Aramchol, 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 or any future product candidates, 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 Aramchol 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.

If we or any of our independent contractors, consultants, collaborators, manufacturers, or service providers fail to comply with healthcare and data privacy laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are or may in the future be subject to federal, state, and foreign healthcare and data privacy laws and regulations pertaining to, among other things, fraud and abuse of patients' rights. These laws and regulations include:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. This statute has been interpreted to apply broadly to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. In addition, the Affordable Care Act amended the Social Security Act to provide that the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor.

- The federal civil False Claims Act, or FCA, prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a "whistleblower" to bring actions on

behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. The FCA prohibits anyone from knowingly presenting, conspiring to present, making a false statement in order to present, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This law also prohibits anyone from knowingly underpaying an obligation owed to a federal program. Increasingly, U.S. federal agencies are requiring nonmonetary remedial measures, such as corporate integrity agreements in FCA settlements. The U.S. Department of Justice announced in 2016 its intent to follow the "Yates Memo," taking a far more aggressive approach in pursuing individuals as FCA defendants in addition to the corporations. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $5,500 to $11,000 per false claim or statement ($10,781 to $21,563 per false claim or statement for penalties assessed after August 1, 2016 for violations occurring after November 2, 2015, and $10,957 to $21,916 per false claim or statement for penalties assessed after February 3, 2017 for violations occurring after November 2, 2015). Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program.

The federal False Statements Statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services.

- The federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- The federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis;

- State laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal;

- Payors requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- In the European Union, the General Data Protection Regulation, or GDPR,—Regulation EU 2016/679—was adopted in May 2016 and became applicable on May 25, 2018, or GDPR. The GDPR further harmonizes data protection requirements across the European Union member states by establishing new and expanded operational requirements

for entities that collect, process or use personal data generated in the European Union, including consent requirements for disclosing the way personal information will be used, information retention requirements, and notification requirements in the event of a data breach.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or foreign regulatory authorities, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Our employees, principal investigators, consultants, commercial partners or vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are also exposed to the risk of employees, independent contractors, principal investigators, consultants, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, commercial partners and vendors could include intentional failures to comply with EU regulations, to provide accurate information to the EMA or EU Member States authorities or to comply with manufacturing or quality standards we have or will have established. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices such as promotion of products by medical practitioners. The EU Member States in which we operate have different statutory provisions regulating the cooperation of pharmaceutical companies with healthcare professionals. In addition to these statutory provisions, codes of conduct issued by business associations or other non-statutory standards may be applicable to our activities. Both statutory provisions and non-statutory codes or standards restrict payments or other benefits provided to healthcare professionals, and in case of non-compliance, may result in severe sanctions such as bans, administrative fines, criminal fines or even imprisonment. The advertising of medicinal products for human use in the EU is regulated by Title VIII of European Directive 2001/83/EC. These provisions have been implemented into the law of the EU member States. Such laws inter alia restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious and irreparable harm to our reputation.

This could also apply with respect to data privacy. In the EU, the EU Directive 95/46/EEC was replaced by the GDPR on May 25, 2018. The GDPR as an EU regulation does not have to be implemented into Member States' national law, but applies directly in all Member States since May 25, 2018. It applies to companies with an establishment in the European Economic Area (EEA) and to certain other companies not in the EEA that offer or provide goods or services to individuals located in the EEA or monitor individuals located in the EEA. The GDPR implements more stringent operational requirements for controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, increased cyber security requirements, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained a valid legal basis for certain data processing activities. The GDPR provides that EU Member States may continue to make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in continued or new differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. We are also subject to evolving and strict rules on the transfer of personal data out of the European Union to the United States. Further prospective revision of the Directive on privacy and electronic communications (Directive 2002/58/EC), or ePrivacy Directive, may affect our marketing communications.

We are in the process of implementing policies and procedures to ensure compliance with the GDPR and its requirements. Our actual or alleged failure to comply with this regulation, or to protect personal data, could result in enforcement actions and significant penalties against us, which could result in negative publicity, increase our operating costs, subject us to claims or other remedies and have a material adverse effect on our business, financial

condition, and results of operations. It is not always possible to identify and deter misconduct by employees or other parties. The precautions we take to detect and prevent such activity may not protect us from legal or regulatory action resulting from a failure to comply with applicable laws or regulations. Misconduct by our employees, principal investigators, consultants, commercial partners or vendors could result in significant financial penalties, criminal sanctions, civil law claims and/or negative media coverage, and thus have a material adverse effect on our business, including through the imposition of significant fines or other sanctions, and our reputation. In particular, failure to comply with EU laws, including failure under the GDPR, ePrivacy Directive and other laws relating to the security of personal data may result in fines up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, if greater, and other administrative penalties including criminal liability, which may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the GDPR and related laws may also give risk to increase risk of private actions, including a new form of class action that is available under the GDPR.

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 register with FDA or foreign regulators undergo regulatory inspection of their manufacturing facilities, processes and quality systems. In addition, pharmaceutical manufacturing facilities are subject to periodic inspection by the FDA and foreign regulatory authorities 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 meet local, federal, or international regulatory requirements either at the outset or on an ongoing basis, in a cost effective manner, if at all.

We do not intend to engage in the manufacture of Aramchol other than for pre-clinical 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 Aramchol. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding foreign regulators to ensure continuing compliance with applicable requirements. Any failure to comply with FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop and market Aramchol and any future product candidates.

If a third-party manufacturer with whom we contract is unable to comply with manufacturing requirements, we may be subject to fines, unanticipated compliance expenses, recall or seizure of Aramchol or any future product candidates, 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 potential product candidate that we develop may be rendered suboptimal, noncompetitive or obsolete.

There are a number of products in development for NASH, many of which are being developed by pharmaceutical companies that are far larger than us, with significantly greater resources and more experience than us in all aspects of drug development and commercialization. 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 future 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 potential product candidates that we develop suboptimal, 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 advanced clinical programs. The majority of our competitors include, but are not limited to, Intercept Pharmaceuticals, Inc., Genfit S.A., Gilead Sciences, Inc., Allergan, Plc., Madrigal Pharmaceuticals Inc., Conatus Pharmaceuticals Inc., Novartis, CymaBay Therapeutics and Viking Therapeutics among others. See also "Item 4. Information on the Company—Competition." Moreover, several additional companies have reported the commencement of research projects and proof-of-concept

trials related to NASH, including those mentioned in the preceding sentence.

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

Aramchol and any future 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 Aramchol and any future 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 Aramchol and any future product candidates, could lead to product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with Aramchol and any future product candidates. 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 or other regulatory actions;
- 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 future product candidates, for which we obtain marketing approval.

If we are unable to obtain adequate insurance with respect to our clinical trials against 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 cover loss or claims by third parties. To the extent our business suffers any 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 Aramchol and any future 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 Aramchol and any future product candidate's programs.

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

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to recruit, attract, retain, manage and motivate qualified senior executive officers with adequate operational, scientific and technical experience. The loss of the services of our senior executive officers, including our President and Chief Executive Officer, Chief Medical Officer, and Chief Scientific Officer, 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. 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 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 the JOBS Act, because we are taking advantage of the exemptions contained in the JOBS Act. We will remain an emerging growth company until, subject to certain conditions, the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (i.e. December 31, 2019), (b) in which we have total annual gross revenue of at least $1.07 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 may 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. Although we have a relatively small number of employees, as we prepare for the ARMOR Study we have been increasing our operations, including expanding our employee base of managerial, operational, clinical and financial personnel. Any future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To that end, we must be able to, 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 Aramchol and any 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 Aramchol and any future product candidates.

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 volatile and unpredictable global economic situations, 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.

Additional clinical trials may divert a significant amount of Company resources and may ultimately be unsuccessful.

We are seeking to expand our clinical operations for Aramchol to multiple other indications in order to expand our pipeline, commercial potential and ultimately de-risk the Company for the success of any one given trial. If we initiate additional clinical trials, this may divert a significant amount of Company resources and may be unsuccessful.

Risks Related to Our Reliance on Third Parties

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

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 Aramchol and any future 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 will be required to change the finished product manufacturer, we may encounter significant delay and likely significant additional cost.

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

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

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

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

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

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

We intend to seek collaboration arrangements with pharmaceutical or biotechnology companies for the continued development and commercialization of our current and potential future product candidates. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority. Moreover, collaborations with pharmaceutical or biotechnology companies and other third parties are often terminated or allowed to expire by the other party. Any lack of effort or ability by our collaborators or any such disagreement, termination or expiration could adversely affect us financially and could harm our business reputation.

We depend on third parties to conduct our clinical trials.

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to oversee most of the operations of our clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a

timely fashion or in accordance with regulatory requirements. If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our financial results and the commercial prospects for Aramchol or any other potential product candidates could be harmed, our costs could increase and our ability to obtain regulatory approval and commence product sales could be delayed.

Risks Related to Our Intellectual Property

The failure to obtain or maintain patents, licensing agreements and other intellectual property rights that are sufficiently broad and protective could impact our ability to compete effectively.

To compete effectively, we must develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. We cannot predict the scope and extent of patent protection for Aramchol because the patent positions of pharmaceutical products are complex and uncertain. Therefore, the degree of future protection for our proprietary rights in our core technologies and any product candidates or products that might be developed using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include, but are not limited to, the following:

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

- we may be subject to interference, reexamination, *inter pares* review, or post-grant review proceedings in the U.S.;

- we may be subject to opposition proceedings in certain foreign countries;
- any patents that are issued may not provide meaningful protection for any significant period of time, if at all;
- any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
- we may not be able to develop additional proprietary technologies that are patentable;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be other patents or pending patent applications existing in the patent landscape that will affect our freedom to operate for Aramchol;
- other companies may challenge and invalidate patents licensed or issued to us or our customers;
- a court could determine that a competitor's technology or product does not infringe our patents;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- if we are not awarded patents or if issued patents expire or are declared invalid or not infringed, there may be no protections against competitors making generic equivalents;
- enforcement of patents is complex, uncertain and expensive, and our patents may be found invalid or enforceable;
- our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- if we encounter delays in our development or clinical trials, the period of time during which we could market Aramchol under patent protection would be reduced.

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

The composition of matter patents directed to Aramchol will expire on March 25, 2019 worldwide. We will not be able to submit an NDA seeking approval of Aramchol prior to the composition of matter patents' expiration date. However, because Aramchol is regarded as a new chemical entity, or NCE, following approval of an NDA, if we are the first applicant to obtain NDA approval, we may be entitled to up to five years of patent term extension in the United States with respect to such NCE, and provided that the use patent with respect to Aramchol in the treatment of fatty liver will still be in force when the approval of the NDA is received from the FDA. The non-extended patent term for such use patent, is due to expire on April 15, 2022 worldwide and on April 17, 2021 in Israel. The U.S. patent was extended by a patent term adjustment of 567 days, resulting in an effective expiration date in the U.S. of November 3, 2023. Analogous mechanisms for protecting the interests of innovator drug companies to compensate for regulatory review and other hurdles they must overcome, of varying duration, may be available in Europe and other foreign jurisdictions. In addition, a term of data exclusivity of up to 5 years will be available for the first approved clinical use of this NCE in the U.S. and for longer periods in other jurisdictions, if Aramchol receives regulatory approval. Although we believe that we may be able to protect our exclusivity in our field of activity through such use patent portfolio and such period of exclusivity, the lack of composition of matter patent protection may diminish our ability to maintain a proprietary position for its intended uses of Aramchol. Moreover, we cannot be certain that we will be the first applicant to obtain an FDA approval for any indication of Aramchol and we cannot be certain that we will be entitled to NCE exclusivity.

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

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

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

As part of our research and development studies, we have confirmed that several Aramchol salts have improved solubility as compared to the existing form of Aramchol acid. In 2014, we submitted new patent applications to protect such salts. Should we decide to develop the formulations of Aramchol salts, we will need to conduct an appropriate bioequivalence study, or studies, of the biological equivalence of two proprietary preparations of a drug.

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

There can be no assurance that the U.S. Patent and Trademark Office, or the USPTO, will issue any patents based on the patent applications that we submitted to protect our Aramchol salts, nor, should the USPTO issue any patents to us with respect to the Aramchol salts, that we will be provided with adequate protection against potentially competitive products. Furthermore, if the USPTO issues us one or more patents for the Aramchol salts, there can be no assurance that the issued patents will be of any commercial value, or that private parties or competitors will not successfully

challenge these patents or circumvent these patents in the United States or their counterparts abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us because we expect Aramchol will be manufactured and used in a number of foreign countries.

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

Although most jurisdictions in which the Company has applied for, intends to apply for, or has been issued patents have patent protection laws similar to those of the United States, some of them do not. For example, the Company expects to do business in South America, Eurasia, China and Indochina in the future and the countries in these regions may not provide the same or similar protection as that provided in the United States.

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

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

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

We may infringe the intellectual property rights of others, which may prevent or delay Aramchol or any future product candidate's development efforts and stop us from commercializing, or increase the costs of commercializing, Aramchol or any future product candidates.

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

Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third-party patents are valid, enforceable and cover Aramchol and any future product candidates or their use, the holders of any of these patents may be able to block our ability to commercialize Aramchol and any future product

candidates unless we obtained a license under the applicable patents, or until the patents expire. In addition to litigation proceedings which may be filed against us, we may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of Aramchol or any future product candidates or lead to prohibition of the manufacture or sale of products by us.

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

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

We also rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with Aramchol or any future product candidates or cause additional material adverse effects upon our competitive business position.

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

Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could impact our future profitability.

We generally enter into non-competition agreements with our employees and certain key consultants, or our employment and consulting agreements contain non-competition provisions. These agreements, to the extent they are in place and in effect, prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

In addition, under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Recent case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patent Law). Although we generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and former employees, or be forced to litigate such claims, which could negatively affect our business.

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

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

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

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

In addition, our patents and patent applications could face challenges. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management's time and attention.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect Aramchol or any future product candidates.

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

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

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

Risks Related to Ownership of Our Ordinary Shares

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;
- 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 of directors, 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.

In addition, the stock market in general, and the Nasdaq Capital Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of our Company and that of small companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly. Price volatility of our ordinary shares might be worse if the trading volume of our ordinary shares is low. Following periods of market volatility or a material decrease in the value of our common shares, shareholders may institute securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. Future sales of our ordinary shares could also reduce the market price of such stock. Any adverse determination in litigation could also subject us to significant liabilities.

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

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

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

Our President and Chief Executive Officer along with our principal shareholders, beneficially own approximately 34% of our outstanding ordinary shares, as of December 31, 2018. Therefore, our principal shareholders will be able to exert significant control over matters submitted to our shareholders for approval.

Our President and Chief Executive Officer along with our principal shareholders, currently beneficially own approximately 34% of our outstanding ordinary shares as of December 31, 2018. Therefore, our principal shareholders will be able to exert significant control over matters submitted to our shareholders for approval. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders. This significant concentration of share ownership may adversely affect the trading price for our ordinary shares because investors often perceive disadvantages in owning stock in companies with controlling shareholders.

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

Sales of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ordinary shares. To date, the lock-up period has expired and substantially all of our outstanding shares are eligible for unrestricted sale. Sales of shares by these shareholders would likely result in the supply of our ordinary shares far exceeding the demand for our ordinary shares and could have a material adverse effect on the trading price of our ordinary shares.

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

We may seek additional capital through a combination of private and public equity offerings, “at-the-market” issuances, equity-linked and structured transactions, debt (straight, convertible, or otherwise) financings, collaborations and licensing arrangements. Under our existing “at the market” equity offering program, or the ATM Offering, as of December 31, 2018, we may sell, from time to time, up to approximately $32.0 million of additional ordinary shares. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us. Depending upon market liquidity at the time, additional sales of shares registered at any given time could cause the trading price of our ordinary shares to decline.

Our U.S. shareholders may suffer adverse tax consequences due to our classification as a passive foreign investment company).

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average value of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Based upon our review of our financial data, we believe that we were not a PFIC for our 2018 taxable year however we expect to be a PFIC for the 2019 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we will be a PFIC in 2019 or for any other taxable year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder (as defined below) owns ordinary shares, such U.S. Holder could face adverse U.S. federal income tax consequences. For example, such U.S. Holder could be subject to additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition of our shares, whether or not we continue to be characterized as a PFIC. Certain adverse consequences of PFIC status can be mitigated if a U.S. Holder makes an election to treat us as a qualified electing fund, or QEF However, it is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election. See also “Item 10. Additional Information—E. Taxation— Certain U.S. Federal Income Tax Considerations.”

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

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

company, we are not required to comply with the auditor attestation requirements of Section 404 for up to five fiscal years after the date of our initial public offering. See "Item 5. Operating and Financial Review and Prospects—Jumpstart Our Business Startups Act of 2012" for more detail regarding our status as an emerging growth company.

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.

If the securities analysts that currently cover our stock, or will do so in the future, or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could be negatively impacted.

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

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

We have never declared or paid cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Moreover, the Israeli Companies Law, 5759-1999, or the Companies Law, imposes certain restrictions on our ability to declare and pay dividends. See "Item 8. Financial Information—Consolidated Financial Statements and Other Financial Information—Dividend Policy" for additional information.

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act, the listing requirements of the Nasdaq Capital Market, on which our ordinary shares are traded, and other applicable securities rules and regulations. The Exchange Act requires that we file periodic reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and the Nasdaq Capital Market may also impose various additional requirements on public companies. As a result, we incurred and will continue to incur additional legal, accounting and other expenses that we did not incur as a privately-held company, particularly after we are no longer considered an "emerging growth company" as defined in the JOBS Act. Further, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our development plans. We have made and will continue to make changes to our corporate governance standards, compensation policy, disclosure controls and financial reporting and accounting systems to meet our reporting obligations and applicable law. The measures we take, however, may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our ordinary shares, fines, sanctions and other regulatory action and potentially civil litigation.

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

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

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

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

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

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

We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares, and our share price may become more volatile and decline.

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

As a "foreign private issuer," we are permitted to, and currently do, follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the Nasdaq Capital Market, or the Nasdaq Listing Rules, for domestic U.S. issuers. For instance, we currently follow home country practice in Israel with regard to, among other things, director nomination procedure and approval of compensation of officers. In addition, we may follow our home country law instead of the Nasdaq Listing Rules that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Capital Market may provide less protection to you than what is accorded to investors under the Nasdaq Listing Rules applicable to domestic U.S. issuers. See "Item 16G. Corporate Governance."

In addition, as a "foreign private issuer," we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements and certain individual executive compensation information, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Furthermore, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year and U.S. domestic issuers that are large accelerated filers are required to file their annual report on Form 10-K within 60 days after the end of each fiscal year. Additionally, as a "foreign private issuer," we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies reduce the frequency and scope of information and protections to which you are entitled as an investor.

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

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

such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

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

Risks Related to Israeli Law and Our Operations in Israel

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

Our executive offices are located in Tel Aviv, Israel. In addition, the majority of our officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. In recent years, these have included hostilities between Israel and Hezbollah in Lebanon and Hamas in the Gaza strip, both of which resulted in rockets being fired into Israel, causing casualties and disruption of economic activities. In addition, Israel faces threats from more distant neighbors, in particular, Iran.

Since February 2011, riots and uprisings in several countries in the Middle East and neighboring regions have led to severe political instability in several neighboring states and to a decline in the regional security situation. Such instability may affect the local and global economy, could negatively affect business conditions and, therefore, could adversely affect our operations. To date, these matters have not had any material effect on our business and results of operations; however, the regional security situation and worldwide perceptions of it are outside our control, and there can be no assurance that these matters will not negatively affect us in the future. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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

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

Our operations may be disrupted as a result of the obligation of Israeli citizens to perform military service.

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

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

Our functional currency is the U.S. dollar. We incur expenses in U.S. dollars, Euros and New Israeli Shekels, or NIS. As a result, we are exposed to the risks that the Euro and the NIS may appreciate relative to the U.S. dollar, or, if either the Euro and the NIS devalue relative to the U.S. dollar, that the inflation rate in the EU and in Israel may exceed such rate of devaluation of the Euro and the NIS, or that the timing of such devaluation may lag behind inflation in the EU and in Israel. In any such event, the U.S. dollar cost of our operations in the EU and in Israel would increase and our U.S. dollar-denominated results of operations would be adversely affected. The average exchange rate for the year ended December 31, 2018 was $1.00 = Euro 1.17 and $1.00 = NIS 3.59. We cannot predict any future trends in the rate of inflation in the EU and in Israel or the rate of devaluation, if any, of either the Euro or the NIS against the U.S. dollar. As of the date hereof, neither the inflation rate in the EU nor in Israel has exceeded the rate of devaluation of the Euro or the NIS, respectively, during the calendar years 2016, 2017 or 2018.

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

The Companies Law regulates, among others, mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. See "Item 10. Additional Information—B. —Mergers and Acquisitions under Israeli Law" for additional information.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. See "Item 10. Additional Information—E. Taxation—Certain Israeli Tax Considerations" for additional information.

Moreover, the classification of our Board into three classes with terms of approximately three years each, per our Articles, the requirement of affirmative vote of at least 75% of the voting rights of the Company represented personally or by proxy and voting thereon at a general meeting in order to amend or replace our Articles and the requirement under the Companies Law to have at least two external directors who cannot readily be removed from office, together with the other provisions of the Articles and Israeli law, could deter or delay potential future merger, acquisition, tender or takeover offers, proxy contests or changes in control or management of the Company.

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 annual report 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.

Your rights, liabilities and responsibilities as a shareholder will be governed by Israeli law and differ in some material respects from those under U.S. law.

Because we are an Israeli company, the rights and responsibilities of our shareholders are governed by our Articles and Israeli law. These rights, liabilities and responsibilities differ in some material respects from the rights, liabilities and responsibilities of shareholders in a U.S. corporation. In particular, a shareholder of an Israeli company has a duty to act in good faith towards the company and other shareholders and to refrain from abusing his, her or its power in the company, including, among other things, when voting at the general meeting of shareholders on certain matters. Israeli law provides that these duties are applicable to shareholder votes on, among other things, amendments to a company's articles of association, increases in a company's authorized share capital, mergers and interested party transactions requiring shareholder approval. In addition, a controlling shareholder, a shareholder who knows that it possesses the power to determine the outcome of a shareholders' vote or a shareholder who has the power to appoint or prevent the appointment of a director or executive officer in the company, has a duty of fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. There is little case law available to assist in understanding the implications of these provisions that govern shareholder behavior. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations. See "Item 10. Additional Information—B Memorandum and Articles of Association—Shareholder Duties" for additional information.

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

ITEM 4. Information on the Company.

A. Historical Background and Corporate Structure

Our Company, Galmed Pharmaceuticals Ltd., was incorporated in Israel on July 31, 2013 as a privately held company and is governed by the Companies Law. 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, GHI. GHI held all of the equity rights in and to GTTI. GTTI held all of the equity rights in and to GIL (other than 0.1% of the share capital held by GHI). GIL held all of the equity rights in and to 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 intangible assets (including our intellectual property) were transferred from GIL to GRD. The Reorganization was effectuated 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 is an inactive company; and (3) GTTI, which was liquidated in 2017. GIL holds GMR, which became an inactive company in 2015 and was liquidated in February 2019. 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, 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.

The following is a diagram of our corporate structure (following GTTI's liquidation):

On March 18, 2014, we completed our initial public offering and since then have been listed on the Nasdaq Capital Market under the symbol “GLMD”.

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 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 annual report. We have included our website address in this annual report solely as an inactive textual reference. Puglisi & Associates, or Puglisi, serves as our authorized representative in the United States for certain limited matters. Puglisi’s address is 850 Library Avenue, Newark, Delaware 19711.

We use our website (http://www.galmedpharma.com) as a channel of distribution of Company information. The information we post through this channel may be deemed material. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not, however, a part of this annual report.

Other than as described in “Item 5. Operating and Financial Review and Prospects—Contractual Obligations”, we have not had any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, since January 1, 2014. Additionally, we have not had any material capital divestitures since January 1, 2014.

B. Business Overview

We are a clinical-stage biopharmaceutical company focused on the development of the liver targeted stearoyl-coenzyme A desaturase-1, or SCD1, modulator Aramchol, a first in class, novel, oral therapy for the treatment of NASH for variable populations, as well as other liver associated disorders. We believe that our product candidate, Aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that constitutes a large unmet medical need.

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, improving fatty acid oxidation and regulating the transport of cholesterol. The ability of Aramchol to decrease liver fat content may also reduce the inflammation and fibrosis in the liver and the risk of cardiovascular complications associated with NASH. Pre-clinical studies suggest Aramchol effect on fibrosis is also direct via collagen production from human hepatic stellate cells. We believe that Aramchol’s ability to reduce liver fat and liver fibrosis and the safety profile observed to date will enable it to be a safe and effective treatment for all stages of NASH in patients who are overweight or obese and have pre

diabetes or type II diabetes mellitus and prevent the hepatic complications associated therewith.

On June 12, 2018, we announced top-line, 52-week results from our global Phase 2b ARREST Study, a multicenter, global, randomized, double-blind, placebo controlled dose-ranging study. A total of 247 patients (approximately one third in the US, one third in Latin America and one third in Europe and Israel) with liver biopsy-proven NASH who were overweight or obese and had pre-diabetes or type II diabetes mellitus were randomized. Patients were randomized in a ratio of 2:2:1 (600mg, 400mg and placebo) taking once-daily oral Aramchol (in the Aramchol treatment arms) or a placebo (in the placebo arm). The treatment part of the trial was 12 months in duration and patients completing this phase were observed for a three month follow-up period. While the we did not meet the primary endpoint of the study, results for the two biopsy endpoints, which may currently constitute a primary endpoint for a Phase 3 trial to support an NDA to the FDA, demonstrated the following: (i) significantly more patients treated with Aramchol 600mg vs. placebo achieved NASH resolution without worsening of fibrosis (16.7% vs. 5.0%; p=0.0514); and (ii) a higher proportion of patients showed at least one-point improvement in fibrosis score without worsening of NASH in Aramchol 600mg vs. placebo (29.5% vs. 17.5%; p=0.2110). At 52 weeks of treatment, Aramchol continued to show a favorable safety and tolerability profile. We are currently focused on preparing for an end of Phase 2b meeting with the FDA to discuss the results of the ARREST Study and a Phase 3/4 ARMOR study protocol, with a view to initiating a Phase 3/4 clinical study of Aramchol in 2019. If the Phase 3/4 trial is initiated and the Phase 3 portion is successful, we intend to submit an NDA to the FDA for the approval of Aramchol for the treatment of NASH in the United States.

Recently, we conducted a Phase I, open-label, two-period, randomized, crossover PK study to assess whether dose splitting of Aramchol 600mg to twice daily 300mg will significantly increase plasma levels. Results of the study showed that the administration of Aramchol 300 mg twice daily resulted in 24-hour plasma concentrations significantly greater than those observed with the administration of Aramchol 600 mg once daily. (P<0.0001).

Non-Alcoholic Fatty Liver Disease (NAFLD) / Non-Alcoholic Steato-Hepatitis (NASH)

It is estimated that the global prevalence of Non-Alcoholic Fatty Liver Disease (NAFLD), the precondition to NASH, is approximately 25% in the general population and much higher in certain high risk groups. This disease is also now recognized as one of the most common liver disorders, and a significant growing public health problem. In the US alone, 80-100 million people are said to be affected by NAFLD, and its prevalence is rapidly growing in parallel with metabolic syndromes, particularly obesity and diabetes.

NAFLD is characterized by the accumulation of fat of 5% or greater in the liver of people who drink alcohol only in moderation, or not at all. There may be numerous causes of NAFLD, however, the disease is mostly associated with a high fat, fructose-rich diet. Although NAFLD is generally asymptomatic, it is a major risk factor for liver inflammation (NASH) and scarring (fibrosis and cirrhosis). In addition, NAFLD is also associated with metabolic syndrome and cardiovascular disease. Currently, NAFLD can only be managed through lifestyle improvements, such as weight reduction and physical activity.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 2% to 4% globally, and is associated with increased risk of liver cirrhosis, liver failure, hepatocellular cancer, as well as metabolic and cardiovascular diseases. The major characteristics of NASH are elevated liver fat, inflammation, ballooning and fibrosis.

However, despite the growing need, there are currently no approved therapeutic treatments for NASH. Modification of risk factors, such as obesity and hyperlipidemia, and proper diabetic control is generally recommended for the treatment of NASH, and the standard of care includes lifestyle changes to promote weight loss, including low-calorie, low-fat diets and physical activity. Although weight loss can be potentially significant in delaying the progression of NASH, studies have shown that, for most individuals, it is generally very difficult to maintain over the long-term, even following bariatric surgery.

There are currently no drugs approved by regulatory authorities for the treatment of NASH. Even though certain drugs, such as insulin sensitizers and antihyperlipidemic agents, are prescribed for some NASH patients, they are not approved for the treatment of NASH and their efficacy has not been proven in adequate and well-controlled clinical studies.

Currently, it is impossible to predict which of the NAFLD patients will deteriorate to NASH as it is unclear what causes NASH to develop. Researchers are now focusing on several factors that may contribute to the development of NASH. Therefore, lifestyle changes are recommended for all patients with NAFLD.

There is an exceptionally wide range of estimates regarding the potential commercial market for NASH. This uncertainty stems from (i) the overall size of the patient population, (ii) the percentage of the addressable market that will be diagnosed and, subsequently, seek treatment, (iii) the ultimate cost of the therapies, (iv) the number of approved drugs for NASH and their profile. Some of these factors cannot be known until NASH drugs begin to hit the market, which based on analysts' estimates, will likely be 2020 or 2021 at the earliest or biomarkers replacing the biopsy diagnosis are validated. Independent estimates generally estimate a commercial multi billion market in developed countries, though we do not endorse any estimates, which are based on a number of different underlying assumptions.

Aramchol for NASH

Overview

Our product candidate, Aramchol, is a first-in-class synthetic fatty acid-bile acid conjugate molecule, or FABAC, molecule that we are developing for oral treatment for NASH in patients who are overweight or obese and have prediabetes or type II diabetes mellitus.

Early in its development, Aramchol's ability to modulate hepatic lipid metabolism was observed and validated in numerous pre-clinical trials with different animal species. Mice fed a high fat diet and treated with Aramchol did not develop fatty liver as compared to non-treated mice. In these early studies, we also observed that the mechanism of this effect was not a result of malabsorption of fat in the intestines because the FABAC-treated mice gained weight throughout the test periods to a similar degree to the control mice. This led us to conclude that FABAC therapy triggers a beneficial modulation of intra-hepatic lipid metabolism and reduces liver fat content.

In *in-vitro* and in vivo studies, Aramchol down regulates the SCD1 enzyme, an enzyme recognized as playing an important role in the metabolism of fatty acids. The SCD1 enzyme is essentially the gateway that regulates the use and storage of fat in the body by converting saturated fatty acids to monounsaturated fatty acids. Experimental animal studies showed that complete inhibition of the SCD1 enzyme protects against diet-induced obesity, hepatic steatosis, or fatty liver, and insulin resistance by instructing the body to use, rather than store, all fatty acids. However, various animal studies have indicated that such complete SCD1 enzyme inhibition has mechanism based serious side effects, such as atherosclerosis, and eye and skin disorders. As observed by us in our pre-clinical and clinical studies performed to date, and subsequently published in the European Journal of Gastroenterology and Hepatology and Archives of Medical Research in 2008 and 2010 respectively, one of Aramchol's unique characteristics is that it down regulates the SCD1 enzyme but does not inhibit it completely – a partial effect. To date, side effects that have been observed in animals with knock out of SCD1 have not been observed in our toxicology and clinical studies.

To better understand the role of Aramchol in NASH, we analyzed the effect of Aramchol in MCD diet model. The aim of this study was to investigate Aramchol's mechanism of action and its effect on fibrosis using the methionine- and choline-deficient (MCD) diet model of NASH. We collected liver and serum from mice fed a MCD diet containing 0.1% methionine (0.1MCD) for four weeks, which developed steatohepatitis and fibrosis, as well as mice receiving a control diet; the metabolomes and proteomes were determined. 0.1MCD fed mice were given Aramchol (5mg/kg/day for the last 2 weeks); liver samples were analyzed histologically. Aramchol administration was found to reduce features of steatohepatitis and fibrosis in 0.1MCD fed mice. Aramchol downregulated the SCD1 enzyme, a key enzyme involved in triglyceride biosynthesis whose loss enhances fatty acid -oxidation. In addition, Aramchol increased the flux through the transsulfuration pathway, leading to a rise in glutathione (GSH) and GSH/GSSG ratio, the main cellular antioxidant that maintains intracellular redox status. Comparison of the serum metabolomic pattern between 0.1MCD-fed mice and patients with NAFLD showed a substantial overlap. These findings were published in Hepatology Communications, Vol. 1, No. 9, 2017.

As the effect of Aramchol on fibrosis was first reported we further analyzed the direct effect of Aramchol on collagen production and reported down regulation of collagen production from the hepatic stellate cells (HSCs) by Aramchol. With that we could conclude that Aramchol has potential direct effect on collagen production and therefore reduces fibrosis indirectly by down regulation of steatosis by reducing the sequence of events but also directly affecting collagen producing cells. These findings were published in Hepatology Communications, Vol. 1, No. 9, 2017.

These findings led us to further analyze the effect of Aramchol using the Thiocatemide (TAA) rat model. TAA is the most commonly used toxic agents to induce liver fibrosis. Repeated IP injections of TAA leads to sever fibrosis / cirrhosis. Among all models for fibrosis, the TAA model share multiple characteristics with human liver fibrosis and is considered to best predict efficacy in humans. Results demonstrated that treatment with Aramchol 5mg/kg, significantly prevented TAA induced fibrosis in a dose dependent manner. These findings were presented at EASL, Amsterdam in April 2017 (The anti Fibrotic effect of Aramchol on liver Fibrosis in TAA animal model).

Phase 1 Single and Multiple-Dose Study of Aramchol in Healthy Male Volunteers (NCT00776841)

Aramchol was evaluated in two Phase 1 clinical trials (under a single protocol) to study its safety, tolerability and PK profile in healthy volunteers, in both single and multiple dose administrations. The first Phase 1 clinical trial was an escalating single-dose trial conducted in 17 healthy subjects testing Aramchol doses ranging from 30 mg to 900 mg, performed in one center in Israel. The subsequent Phase 1 clinical trial was a repeated-dose trial conducted over four days in 25 healthy subjects testing repeated daily doses of Aramchol of 30 mg and 300 mg, performed in one center in Israel. The profiles for the groups were similar and the maximal plasma concentration of Aramchol increased with the higher doses. The PK profile demonstrated that Aramchol is suitable at each dose for once-daily administration and there were neither significant adverse events observed in either Phase 1 trial nor any notable changes in biochemical, hematologic, cardiovascular or other safety parameters.

Phase 2a Trial: Aramchol Treatment in NAFLD or NASH Patients (NCT01094158)

In January 2012, we completed a 60 patient multi-center, randomized, double-blind, placebo-controlled Phase 2a clinical trial of Aramchol in patients with NAFLD or NASH between the ages of 18 and 75 in 12 centers in Israel. The Phase 2a study results were published in July 2014 in the peer-reviewed Clinical Gastroenterology and Hepatology Journal. The trial was performed in patients with either NAFLD or NASH, which design was deemed acceptable by the FDA in 2007 at a pre-IND scientific advisory meeting. The trial's primary efficacy endpoint was a reduction in liver fat content, and did not consider inflammation or fibrosis, which can be diagnosed only by liver biopsy. We believe that the short study duration of three months of treatment followed by a one-month follow-up period did not warrant repeated biopsies. The trial evaluated the effects on liver fat content of 100 mg and 300 mg once-daily doses of Aramchol compared to a placebo. At the end of the three month treatment period, statistically significant reductions in liver fat concentration as measured by MRS were observed in the 300 mg patient group. Specifically, a 12.57% mean liver fat content reduction was observed in the 300 mg group, as compared to a mean reduction of 2.89% in the 100 mg group and a mean increase of 6.39% in the placebo-treated patients. These results indicate that the effects of Aramchol are dose-dependent, as demonstrated in the graph below, which presents the results with respect to the 57 patients who successfully completed the entire treatment period (three patients were excluded from data analysis because of one protocol violation and two withdrawal consents).

Relative Change in MRS from Baseline after Three Months of Treatment

The table above shows that the primary endpoint of the study was attained. The study demonstrated a statistically significant, dose dependent reduction in fat content in the livers of patients treated with Aramchol, with a 19% difference between the 300 mg dose group and the placebo group, while the difference between the 100 mg dose group and the placebo group was not statistically significant. Notably, the minimal effective dose of Aramchol for fat reduction has been defined.

There were no statistically significant differences among the three treatment groups for any of the secondary end points. There was a non-statistically significant trend of mild weight reduction (P=.1) in the high dose Aramchol group. Serum adiponectin levels increased (0.2 ± 1.7 µg/mL) in the high-dose Aramchol group but decreased in the low-dose (-0.3 ± 1.5 µg/mL) and placebo groups (-0.7 ±_1.3 µg/mL) (P= 0.88 for trend of dose-response relationship by linear regression). FMD increased non-statistically significantly by 1.28% ± 2.92% in the high-dose group, by 0.34% ±3.54% in the low-dose group, and by 0.46% ± 2.28% in the placebo group.

The frequency of adverse events was similar in all treatment groups, and none of them were considered to be related to the treatment. All adverse events in the active treatment arms were mild or moderate and none were serious. None of the patients withdrew as a result of adverse events. The following table shows the most frequent adverse events (occurring in ³ 2 patients in any group) in the study.

	Placebo (N=20)			Aramchol 100mg/d (N=20)			Aramchol 300mg/d (N=20)		
MedDRA preferred term	No. Events	No. Subjects	%	No. Events	No. Subjects	%	No. Events	No. Subjects	%
Abdominal pain	2	2	10%	2	1	5 %	1	1	5 %
Abdominal pain upper	1	1	5 %	2	2	10%	-	-	-
Constipation	2	2	10%	-	-	-	-	-	-
Asthenia	2	2	10%	-	-	-	-	-	-
Back pain	3	3	15%	-	-	-	-	-	-
Musculoskeletal pain	2	2	10%	-	-	-	-	-	-
Upper respiratory tract infection	-	-	-	-	-	-	2	2	10%

The results of our Phase 2a clinical trial of Aramchol in the peer-reviewed Clinical Gastroenterology and Hepatology Journal were published in December 2014. The trial manuscript, entitled “The Fatty Acid-Bile Acid Conjugate Aramchol Reduced Liver Fat Content in Patients with Nonalcoholic Fatty Liver Disease,” provides the full report of the Phase 2a trial, which was completed in January 2012 and presented at the 47th Annual Meeting of the European Association for the Study of the Liver in 2012. Based on this Phase 2a proof-of-concept results, we established a development plan that we believe may confirm: (i) the good safety profile of Aramchol, (ii) the optimal dose of Aramchol, and (iii) efficacy on steatosis as well as fibrosis in patients with NASH.

Pharmacokinetics of Single and Multiple Escalating Doses of Aramchol and Food Effect in Healthy Volunteers (NCT02374437)

On April 28, 2014, we commenced PK and food effect studies of Aramchol. In written correspondence from December 2013 regarding a requested pre-IND meeting, the FDA recommended that we conduct such studies prior to commencing our Phase 2b ARREST Study.

We conducted the food effect and PK study at the Sourasky Medical Center in Tel Aviv, Israel involving 66 healthy volunteers to evaluate the PK of Aramchol following single and multiple escalating doses (200 mg, 400 mg and 600 mg), as well as to evaluate the effect of a high-fat, high-calorie meal on the PK of Aramchol following a single dose in healthy volunteers.

The results showed dose-related, but less than dose-proportional, increases in the mean Aramchol plasma concentrations, or Cmax, area under the curve, or AUC, (0-t), and AUC (inf) of 200 mg, 400 mg and 600 mg doses administered under fasting conditions or following a light meal, both at single and repeated dose administration. Cmax and AUC are metrics used to indicate the significance of a drug's exposure. Steady-state was achieved by 144 hours (day seven). Administration of Aramchol after a high-fat, high-calorie meal afforded a 2.6 fold increase in exposure, as measured by Cmax, AUC(0-t), and AUC(inf) compared to the fasting group.

No serious adverse events or deaths occurred during the study. Adverse events were equally distributed between placebo and Aramchol doses, were mild (with only one moderate adverse event) and the majority defined unrelated to Aramchol. The PK study provides additional safety data to further support existing safety data from our pre-clinical studies and our Phase 1 and Phase 2a clinical trials of Aramchol.

Pharmacokinetics of Single and Multiple Escalating Doses of Aramchol Administered under Fed Conditions in Healthy Chinese Volunteers (NCT 02803996)

In 2016, we performed the Chinese PK Study involving Chinese patients who are domiciled in the United States. We enrolled 66 patients in this study, consisting of two parts. In part A, 32 subjects received a single escalating dose; Part B enrolled 34 subjects which received a multiple escalating dose. Dr. Evelyn Darius served as the Study Investigator. No safety signal was identified in this study and we deemed no changes were required in the enrollment of Chinese patients into the ARREST Study. Moreover, having this Chinese PK Study data may give us a head start in future licensing discussions with potential Chinese partners for the development of Aramchol in China.

Phase 2b ARREST Study for Aramchol (NCT 02279524)

In September 2014, the FDA granted Fast Track designation status to Aramchol for the treatment of NASH. Fast Track designation may accelerate the development process and may expedite the review of drugs that show promise in treating serious, life-threatening medical conditions for which no other drug either exists or is as effective.

On February 1, 2015, we began our ARREST Study. The ARREST Study was a Phase 2b, multicenter, global, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety and of two doses of Aramchol for the treatment of NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus. In order to be eligible to participate in the ARREST Study, patients had to be affected by NASH, as diagnosed by a biopsy centrally read (steatosis ≥1 + inflammation ≥1 + ballooning ≥1, total activity NAS score of 4 or more), have a fibrosis stage of 1-3, be overweight or obese as measured by a Body Mass Index between 25 and 40 or waist circumference between 88cm to 200cm for women, and between 102cm to 200cm for men, and who are pre diabetic or type II diabetic. We targeted this specific population as it is at the greatest risk of developing NASH and its complications. We have generated data from animal models that lead us to believe that Aramchol targets all three main pathologies of the disease: steatosis, inflammation and fibrosis.

A total of 247 patients (approximately one third in the US, one third in Latin America and one third in Europe and Israel) with liver biopsy-proven NASH who were overweight or obese and had pre-diabetes or type II diabetes mellitus were randomized. Patients were randomized in a ratio of 2:2:1 (600mg, 400mg and placebo) taking once-daily oral Aramchol (in the Aramchol treatment arms) or a placebo (in the placebo arm). The treatment part of the trial was 12 months in duration and patients completing this phase were observed for a three month follow-up period. In February 2017, we completed randomization of the ARREST Study. Baseline histology of patients enrolled into the ARREST study demonstrated a population with advanced disease, with 60% having stage 2 and 3 fibrosis and 70% have NAS≥5 at baseline.

The primary endpoint of the study was the change from baseline to end of study in liver triglycerides ratio as measured by magnetic resonance spectroscopy, or MRS (Aramchol 600mg vs. placebo). Secondary endpoints, demonstrated through biopsy, included fibrosis improvement by at least one stage or more without worsening of NASH (defined by an increase of inflammation and or ballooning) and NASH resolution (defined by ballooning score 0 and inflammation score 0-1 at termination) without worsening of fibrosis. Other secondary endpoints included improvement (2 points or more) in NASH activity index, as measured by NAS or SAF, without worsening fibrosis and change in baseline to week 52/termination in ALT (U/L).

On June 12, 2018, we announced top-line results of the ARREST Study and on November 13, 2018 an oral abstract presentation of one-year results of the ARREST Study was presented during a Late Breaking Abstract Oral Session at The Liver Meeting® 2018 during the American Association for the Study of Liver Diseases 2018 Annual Meeting.

Of the 247 patients, 48 patients were in the placebo arm, 101 patients in the Aramchol 400mg arm and 98 in the Aramchol 600mg treatment arm. The majority of subjects completed 52 weeks of treatment and 13 weeks of follow up (89.1%, 89.8%, 85.4% in the 400 mg, 600 mg and placebo arms, respectively). The leading cause of discontinuation was consent withdrawal and early termination due to adverse events; the incidence of early termination due to AEs was very low and similar across study arms.

Patients in the ARREST study were planned to undergo MRS, and a liver biopsy at baseline and week 52, which were centrally read, blinded to treatment allocation. The statistical analysis plan included pre-defined analysis sets: (i) a full analysis set for MRI (FAS - MRI): all intent to treat, or ITT, patients with baseline and at least one second MRS. 214 patients were included in this analysis set (41 in placebo; 90 in Aramchol 400mg; and 83 in Aramchol 600mg); and (ii) a full analysis set for liver biopsy (FAS - biopsy): all ITT patients with baseline and a second biopsy. 198 patients were included in this analysis set (40 in placebo; 80 in Aramchol 400mg; and 78 in Aramchol 600mg).

Results from the study showed a statistically significant reduction in liver fat by MRS with Aramchol 400mg vs. placebo (p=0.0450) and not with 600mg (p=0.0655) and thus did not reach the primary endpoint of the study. In a post-hoc analysis, a cutoff of 5% absolute reduction in liver fat was used as a surrogate for potentially clinically meaningful MRI reduction. In this responder’s analysis, a dose-response could be observed; the responder rate was 47.0%, 36.7% and 24.2%, in the Aramchol 600mg, 400mg and placebo arms, respectively. The proportion of the Aramchol 600mg arm compared to placebo was statistically-significant (p=0.0279).

Results for the two biopsy endpoints, which may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application, demonstrated the following: (i) significantly more patients treated with Aramchol 600mg vs. placebo achieved NASH resolution without worsening of fibrosis (16.7% vs. 5.0%; p=0.0514); and (ii) a higher proportion of patients showed at least one-point improvement in fibrosis score without worsening of NASH in Aramchol 600mg vs. placebo (29.5% vs. 17.5%; p=0.2110).

Statistically significant reductions in live enzymes alanine transaminase (ALT) and aspartate transaminase (AST) were demonstrated in both Aramchol arms vs. placebo ($p \leq 0.0002$) and ($p < 0.0001$), respectively.

Secondary endpoints based on NAS and SAF activity score, ≥2 points improvement, showed a higher proportion of patients with improvement in the Aramchol arms (600mg>400mg>placebo; $P > 0.05$).

Exploratory endpoints of glycemic parameters showed statistically significant reductions in HbA1c with both Aramchol arms vs. placebo ($p < 0.007$) implying a potential effect on glycemic control.

At 52 weeks of treatment, Aramchol continued to show a favorable safety and tolerability profile. Serious adverse events were reported in 12.5%, 8.9% and 9.2% of patients in placebo, Aramchol 400mg and 600mg arms, respectively. No clustering of event type or atypical events for the studied population was reported in either Aramchol arms. Severe adverse events were reported in 10.4%, 6.9%, and 6.1% of patients in placebo, Aramchol 400mg, and 600mg arms, respectively. Early terminations due to adverse events occurred in 4.2%, 3.0% and 4.1% in placebo, Aramchol 400mg and 600mg arms, respectively.

The following table summarizes the most frequent adverse events.

The following table summarizes the ARREST results:

	Placebo	Aramchol 400mg	Aramchol 600mg
MRS-Absolute change from baseline in mean liver fat (1)	-0.09 %	-3.41 % P=0.0450	-3.18 % P=0.0655
MRS responders- Reduction of ≥5% in absolute change from baseline (1)	24.4 %	36.7 % P=0.0878	47.0 % P=0.0279
NASH resolution without worsening of fibrosis (2)	5 %	7.5 % P=0.4955	16.7 % P=0.0514
NASH resolution (2)	7.5 %	12.5 % P=0.2237	19.2 % P=0.0462
Fibrosis improvement (≥1 stage) without worsening of NASH (2)	17.5 %	21.3 % P=0.8425	29.5 % P=0.2110
Progression to Cirrhosis (Post-Hoc Analysis) worsening of NASH (2)	7.5 %	7.5 % P=0.5693	1.3 % P=0.1008
ALT (U/L) Change from baseline (3)	+11.82	-12.0 P=0.0002	-17.3 P<0.0001
AST (U/L) Change from baseline (3)	+6.67	-7.20 p=0.0011	-10.83 p<.0001
HbA1C Change from baseline (4)	+0.32	-0.04 p=0.0061	-0.13 p=0.0008

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(1) Placebo N=41; 400mg N=90, 600mg N=83; Mixed Effect Model Repeat Measurement (MMRM) adjusted mean changes from baseline; p-values for comparison of active treatment arm vs. placebo.

(2) Placebo N=40, 400mg N=80, 600mg N=78; Baseline adjusted logistic regression; p-values for comparison of active treatment arm vs. placebo.

(3) Placebo N=47, 400mg N=100, 600mg N=98; MMRM adjusted mean changes from baseline; p-values for comparison of active treatment arm vs. placebo.

(4) Placebo N=47, 400mg N=98, 600mg N=96; MMRM adjusted mean changes from baseline; p-values for comparison of active treatment arm vs. placebo.

Dose Splitting Pharmcokinetic Study (NCT03774173)

As a result of the dose response pattern observed in the ARREST Study, we recently conducted a Phase I, open-label, two-period, randomized, crossover PK study to assess whether dose splitting of Aramchol 600mg to twice daily 300mg will significantly increase plasma levels. 16 healthy subjects took part in two study periods. Eight subjects received each regimen in the first period and the alternate regimen in the second period. A PK profile was obtained over the dosing interval at steady state on day ten of each period.

Results of the study showed that the administration of Aramchol 300 mg twice daily resulted in 24-hour plasma concentrations significantly greater than those observed with the administration of Aramchol 600 mg once daily. ($P<0.0001$). The average plasma levels (exposure) were 53% higher and exposure was greater in all 16 subjects with the twice daily dosing. The treatment in both dosing regimens were similar in terms of safety and were well tolerated.

Planned Phase 3/4 ARMOR Study for Aramchol

We are planning to initiate the ARMOR Study, a Phase 3/4 pivotal study of Aramchol for the treatment of NASH at the end of the second quarter of 2019 or early in the third quarter of 2019, subject to a successful end of Phase 2b meeting and the FDA and other regulatory authorities agreeing with our IND or foreign equivalent, as applicable. The study design takes into consideration draft guidance issued by the FDA in December 2018 entitled “Noncirrhotic Nonalcoholic Steatohepatitis with Liver Fibrosis: Developing Drugs for Treatment”, or the “December Guidance”.

The following is a summary of our planned clinical trial design, which is subject to change.

The planned Phase 3/4 study is a multi-national, multi-center, randomized, double blind, placebo-controlled study designed to evaluate the efficacy and safety of Aramchol 600 mg or twice daily Aramchol 300mg as compared to placebo in subjects with NASH confirmed by liver biopsy who are overweight or obese and who have pre-diabetes or type II diabetes. Subjects will have a baseline fibrosis score of 2-3.

The study is currently designed to consist of two parts. In the first part (histology-based) subjects will undergo biopsy, followed by treatment with Aramchol or matching placebo for 52 weeks until the second biopsy. The primary histology-based endpoint is expected to be NASH resolution without worsening of fibrosis or fibrosis improvement without NASH worsening.

In the second part (clinically-based), subjects will continue with the same treatment assignment until study completion to determine clinical efficacy. The primary clinically-based endpoint is expected to be based on clinical events including all-cause mortality, histological progression to cirrhosis, MELD score >15, and hepatic decompensation events (e.g., hepatic encephalopathy, variceal bleeding, ascites). If the clinical trial results in the first part are positive, we plan to submit an NDA for conditional approval to the FDA.

The following is a depiction of our planned study design:

Additional Pre-clinical and Clinical Studies Required for Regulatory Submissions

Toxicology Studies

Since the completion of the Phase 2a study, pre-clinical toxicology studies have been conducted to support our ongoing clinical programs and regulatory submissions. These studies were performed in compliance with the EMA's ICH M3 (R2) guidelines by WIL Research, a global contract research organization, at its facility in Holland. The toxicity program for Aramchol included repeat dose studies of up to six months in rats and up to nine months in dogs by oral administration, the intended route of administration in the clinical trials and beyond. The dose level of 1000 mg/kg/day in rats and 1500 mg/kg/day in dogs, which is the maximal feasible dose in both species showed no-observed-adverse-effect-level, or NOAEL. There were no observations noted in the rat study. The findings in the dog study were limited to changes in plasma lipids, including decreases in total blood cholesterol levels, LDL, HDL and phospholipids, and a slight increase in the size of the adrenal glands, which were considered to be an extension of the primary pharmacology of Aramchol and non-toxic effects, and skin scales from week 13 onwards in all Aramchol-treated groups, with a dose-related incidence. After six months this was not accompanied by any microscopic alteration of the skin and therefore considered not toxicologically relevant. Results from the study show that after nine months the presence of scales in all Aramchol-treated groups was accompanied by minor test item-related microscopic findings in the skin: Hyperkeratosis of the epidermis, correlating to the scales, and keratin plugs in the hair follicles (in males at 750/500 and 1500 mg/kg). After a 12-week treatment-free recovery period, fewer scales were noted and microscopically there was partial recovery. As these findings were minor and no clinical symptoms like scratching were noted, these findings were considered not adverse.

Aramchol was non-mutagenic in vitro in the Ames test and chromosomal aberrations test, each of which is a test to determine whether the subject chemical can cause mutations in the DNA of an organism. In addition, in bone marrow micronucleus test in male rats at a 2000 mg/kg oral dose (the maximum recommended dose in accordance with ICH S2 (R1)), Aramchol was not clastogenic, meaning it did not give rise to or induce disruption or breakages of chromosomes, nor was it aneugenic, meaning it did not cause the number of chromosomes in the nucleus of a cell to not be an exact multiple of the monoploid number of a particular species.

Embryo-fetal development toxicity was assessed in rats and rabbits. No maternal or fetal development toxicity was observed in either species. The NOAEL for maternal and development toxicity was at least 1000 mg/kg in rats and

750 mg/kg in rabbits (the maximum feasible dose in both species).

No maximum tolerated doses were reached in the studies. Over 50-fold safety margin exposure was achieved in dogs but not in rats. However, for rats, at least three of the four ICH M3(R2) safety margin criteria were met, and for dogs all four criteria were met. Blood tests revealed a decrease in total blood cholesterol levels, including LDL, HDL and phospholipids, and there was a slight increase in the size of the adrenal glands of the dogs, which WIL Research assessed as a physiologic compensatory response to the decrease in blood cholesterol levels. WIL Research did not consider the decrease in blood cholesterol levels or the physiologic response of the adrenal glands as a toxic effect, but rather as a pharmacodynamic effect, which is a biochemical and physiological effect of the drug on the body. Based on the above, WIL Research concluded that the overall safety data for Aramchol is sufficient to support the proposed Phase 2b clinical trial.

Carcinogenicity studies to identify whether Aramchol has any tumorigenic potential upon long-term administration in support of any future NDAs or MAAs are planned to be initiated during 2019. Such carcinogenicity studies are required by regulatory agencies for any pharmaceutical that is intended for continuous clinical use for at least six months. We are currently preparing the necessary information to support a CARC submission to the FDA scheduled for the second quarter of 2019.

Aramchol for the Treatment of Other Indications

On February 14, 2018, we announced topline results from the investigator initiated ARRIVE Study for HIV associated lipodystrophy and NAFLD patients. HIV patients have advanced liver disease which is a major cause for morbidity and mortality. ARRIVE, a Phase 2a, investigator initiated clinical trial conducted at the University of California San Diego by Professor Rohit Loomba was a randomized, double-blinded, placebo-controlled, 12 weeks, proof-of-concept study that evaluated the safety and efficacy of Aramchol at 600mg/day versus placebo in 50 patients with HIV-associated lipodystrophy and NAFLD. The primary end point of successful therapy was improvement in hepatic steatosis at 12 weeks, as measured by MRI-PDFF. Secondary endpoints were improvement in total body fat, metabolic profile, and liver biochemistry. Liver biopsies were not included as part of the evaluation in this pilot trial. The trial showed no difference between HIV patients receiving Aramchol for 12 weeks when compared with HIV patients in the placebo arm. Aramchol showed a favorable safety and tolerability profile. Although the pathology (fatty liver) is similar to “garden variety” NASH, the pathogenesis involved in the HIV lipodystrophy and NAFLD is different and multi factorial including the effect of the virus itself and the anti-HIV medications.

On November 13, 2014, we announced the first administration of Aramchol in a proof-of-concept Phase 2a clinical trial for the treatment of newly formed cholesterol gallstones following bariatric surgery. The primary end-point was to prove that Aramchol dissolves newly formed gallbladder gallstones following bariatric surgery. Patients were to be assigned to one of three treatment arms; 400mg tablets, 600mg tablets and placebo. Only 9 patients were enrolled, and 7 patients completed the study. Due to poor patient recruitment and change in Company focus, we decided to terminate the study on October 1, 2015. We currently believe that it is unlikely that we will revive another study in cholesterol gallstones.

Topical Development

We selected to test Steamchol, in proof of concept studies through a cosmeceutical route of development. Accordingly, on October 13, 2015, Steamchol received a CAS (Chemical Abstracts Service Registry) name and number to allow its cosmeceutical development.

On October 6, 2016, we initiated a proof-of-concept 20-week, double blind, controlled study to evaluate the efficacy and tolerance of Steamchol (a synthetic FABAC, a conjugate of stearic acid (C18:0) and colic acid with similar properties of Aramchol formulated as topical cream), in subjects with Acne Vulgaris. The study was conducted at the IRSI Institute (International Research Services Inc.) in Port Chester, New York, US. A total of 68 subjects participated in the study. On July 2017, top line data was received which was determined to be inconclusive. Due to poor data collection and higher-priority clinical programs, we decided not to pursue this indication. At present, we believe that it is unlikely that we will revive another study in Acne Vulgaris.

Our Competitive Strengths

We believe our key competitive strengths include the following:

- ***A drug that targets the main NASH pathologies; steatosis, inflammation and fibrosis***. We have generated data from animal models that lead us to believe that Aramchol targets all three main pathologies of NASH: steatosis, inflammation and fibrosis. Directly affecting hepatic stellate cells for down regulation of collagen production suggested that Aramchol targets fibrosis directly and therefore has a potential to show significant results in NASH resolution without fibrosis worsening and/or fibrosis improvement without worsening of NASH

- ***600mg dose of Aramchol in ARREST Study demonstrated a significant effect on an endpoint that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application.*** In our recently completed Phase 2b ARREST Study, significantly more patients treated with Aramchol 600mg vs. placebo achieved NASH resolution without worsening of fibrosis (16.7% vs. 5.0%; p=0.0514). Under current FDA guidance, resolution of NASH and no worsening of liver fibrosis on NASH may currently constitute one of two endpoints that support an FDA marketing application. We believe that if we observe a similar effect on patients in our planned ARMOR Study, then we believe Aramchol is well positioned to be approved by the FDA.

- ***An orally delivered drug with a good safety profile.*** In its current formulation, Aramchol is administered orally as a tablet. Simple and convenient oral delivery is expected to lead to increased patient compliance. Together with Aramchol's good safety profile, we believe that Aramchol is well positioned against the competition in the treatment of NASH, where some treatments under development may require intravenous delivery or may cause adverse events, such as itching or an increase in LDL, which can be highly inconvenient for patients with chronic diseases, such as NASH, and may result in low patient compliance. If approved, Aramchol may enable physicians to treat NASH patients with moderate to severe fibrosis in all stages of NASH for long periods of time.

- ***Experienced team with extensive knowledge and expertise in the treatment of liver diseases.*** The Galmed team is highly skilled, experienced, and professional, which enables product development in an efficient, cost effective manner to enable timely regulatory approval. We believe our management team, scientific advisors and personnel have extensive knowledge and experience in the treatment of liver diseases, developing FABACs, such as Aramchol, for the treatment of liver diseases 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 fields of metabolic and liver diseases.

Our Strategy

Our strategy is to build a specialized biopharmaceutical company that develops, in a cost-effective manner, novel molecules from clinical stage to market readiness. We seek to create global partnerships with academic institutions and biotechnology or pharmaceutical companies to effectively collaborate in developing a portfolio and ultimately out-license Aramchol. Through this approach, we have successfully advanced Aramchol into various stages of clinical development. Key elements of our strategy include:

- **Continue advancing Aramchol through development as a first-in-class treatment for NASH**. Following the recent completion of our Phase 2b ARREST Study, we are advancing Aramchol into a Phase 3/4 ARMOR Study with the goal of offering a first-in-class treatment for NASH.

- **Explore NASH sub populations and establish strategic partnerships for Aramchol in different geographies, including China**. We plan on exploring specific NASH sub populations. For example, we plan to conduct a Phase 1/2 NAFLD juvenile population study exploring Aramchol's application in adolescents. In addition, we intend to

strategically partner with pharmaceutical companies that possess experience, resources and infrastructure to execute clinical trial(s), regulatory approval and/or market launch. As part of this strategy, in July 28, 2016, we signed a license agreement with Samil for the commercialization of Aramchol in Korea. See “Item 4. Information on the Company—Business Overview—Strategic Collaborations, Research Arrangements and Other Material Agreements—Samil Pharm. Co., Ltd.” for more information regarding the Samil Agreement. In addition, we are actively exploring strategic partnership opportunities in other Asian countries including China.

- **Investigate possible therapeutic combinations of Aramchol with drugs manufactured by others.** We are seeking to co-develop Aramchol as a best in class drug with drugs manufactured by others in order to increase the commercial opportunities of Aramchol.

- **In-license, develop or acquire additional drug candidates**. To diversify and expand our product pipeline, we evaluate from time to time other drug candidates for in-licensing or acquisition opportunities.

Strategic Collaborations, Research Arrangements and other Agreements

NAFLD Juvenile Population

On September 22, 2016, we entered into an investigator initiated clinical trial agreement, or the UCSD Agreement, with the Regents of the University of California on behalf of its San Diego campus, or UCSD, to conduct a Phase 1/2A study, or the ARTISAN Study, entitled: "A Phase I-IIa Study to Assess Safety, Tolerability, Efficacy, and Pharmacokinetics of Aramchol in a NAFLD Juvenile Population", or the Protocol. The ARTISAN Study (ARamchol Trial to Improve Steatosis in Adolescent NAFLD) will be led by Jeffrey Schwimmer, MD, professor of pediatrics, UC San Diego School of Medicine and Director, Fatty Liver Clinic, Rady Children's Hospital, San Diego. We expect patient enrolment of the ARTISAN Study to commence during 2019.

Pursuant to the terms of the UCSD Agreement, we shall provide our proprietary drug product candidate Aramchol, without cost, to conduct the study as required pursuant to the Protocol and shall provide funds to conduct the ARTISAN Study over the duration of the study.

Under the UCSD Agreement, UCSD has granted us a non-exclusive, royalty-free license to use any UCSD or joint invention and ARTISAN Study data for our internal research and development purposes. Further, UCSD grants us a time-limited first right to negotiate a commercial, royalty-bearing, exclusive license, to make, use, and sell any patentable UCSD or joint invention conceived and reduced to practice in the performance of the research, for the term of any patent thereon.

All rights, title and interest in ARTISAN Study data shall be the sole and exclusive property of UCSD; however, we shall be entitled to make use of such ARTISAN Study data for legal purpose consistent with the informed consent, including publication and regulatory filings, after the earlier of the publication of the ARTISAN Study data by UCSD or upon the expiration of a period of eighteen (18) months from the completion of the ARTISAN Study. The Protocol and research design of the ARTISAN Study are the property of UCSD.

Either party may terminate the UCSD Agreement (i) upon thirty (30) days prior written notice to the other Party, in its sole discretion; (ii) upon written notice to the other Party, if the terminating Party determines that termination of the ARTISAN Study is necessary for the safety of the ARTISAN Study subjects; or (iii) upon the other party's material breach if such party fails to cure such breach within thirty days after receiving written notice thereof. Upon receipt of notice of early termination, UCSD will stop screening subjects for and enrolling subjects in the Study and will discuss in good faith a plan to continue monitoring ARTISAN Study subjects as appropriate and determine an orderly winding down of the ARTISAN Study. Upon termination or expiration of the UCSD Agreement, all CRFs outstanding must be

completed and copies returned to us together with completed ARTISAN Study Drug inventory and records, and all our confidential information. If the UCSD Agreement is terminated before completion of the ARTISAN Study, the parties shall negotiate in good faith on the phase-out for ARTISAN Study subjects and subsequent treatment of ARTISAN Study subjects.

The UCSD Agreement also includes customary indemnification provisions.

Samil Pharma. Co., Ltd.

On July 28, 2016, we entered into a license agreement, referred to herein as the Samil Agreement, with Samil for the commercialization of Aramchol (with the option to manufacture) in the Republic of Korea, or the Territory.

Under the terms of the Samil Agreement, the Company has granted Samil an exclusive licence, or the Samil License, for fatty liver indications including NASH, or the Field of Use, in the Republic of Korea, or the Territory to such information concerning Aramchol as may be required to support Samil's applications for regulatory approvals, or the Licensed Information, and the patents for the import, marketing, use, sale, offer for sale, commercialisation and distribution (and, if the option is exercised, manufacture) of Aramchol in tablet form, or any other physical form as may be produced or manufactured by or on behalf of Galmed or by a third party for Galmed and, if the option set out below is exercised, any products within the Field of Use, the development, manufacture or sale of which is based, in whole or in part, on, or involves the use of, the Licensed Information or covered under any patent, or the Product.

The Samil License shall remain in force with respect to each Product (if the Samil Agreement is not early terminated) until the later of: (i) the date of expiry in the Territory of the last of any patent covering such Product or any formulation, dosing or administration form thereof; and (ii) the date of expiry of a period of 20 years commencing on the date of first commercial sale by Samil or a sublicensee of such Product in the Territory.

Upon the signing of the Samil Agreement, Samil paid the Company a gross upfront fee of approximately $2.1 million and in September], 2018, we received a milestone payment of $1.5 million. Samil has also agreed to pay additional clinical and regulatory-based milestone payments, which may aggregate to an additional $4.5 million, as well as tiered, double-digit royalties payable on sales (lower if sales of a generic equivalent commence in the Territory).

Pursuant to the terms of the Samil Agreement, following the first achievement of US$25 million of net sales in any calendar year following the first commercial sale of the Product in the Territory, Samil shall have the option to request that the Licensed Information include methods for the formulation of Aramchol from its API, to allow for the manufacture of Aramchol by Samil; provided, however, that we shall have the option, to widen the definition of the Licensed Information as aforesaid at any time.

We shall be entitled, at our option: (i) to modify the Samil License with respect to any Product so that it is non-exclusive only; or (ii) to terminate the Samil License hereunder, with respect to any Product if: (a) a first purchasing order from Samil for at least one Product shall not have been placed by 6 months following the grant of the Korean Ministry of Food and Drug Safety new drug approval; or (b) commercial sale of such Product having commenced and either (i) there shall be a period of 1 year during which no sales of any Product shall take place, or (ii) within 1 year of such commencement, aggregate sales of Products shall not have reached a reasonable level, as determined by the joint development committee, in each case, except as a result of force majeure or other factors beyond the control of Samil. Further, we shall be entitled to terminate the Samil Agreement if Samil challenges the validity of any of the patents. If any such challenge is unsuccessful, Samil shall (in addition to our right to terminate) pay us liquidated damages in the amounts of US $8,000,000. Either party may terminate the Samil Agreement (i) upon the other party’s material breach if such party fails to cure such breach within 30 days, or, in the case of failure by Samil to pay any amount due from Samil to us pursuant to or in connection with the Samil Agreement 14 days after receiving written notice thereof, or (ii) upon customary events such as the granting of a winding-up order if such order or act is not cancelled within 60 days.

In the event that we do not achieve the primary endpoint as defined in the study protocol, or Successful Completion, of the ARREST Study, we shall as soon as practicable notify Samil of the non-achievement of such Successful Completion, and within 60 days thereof, notify Samil in writing either: (i) that we have decided not to develop the Licensed Information further for the Field of Use, or the Cessation Notice, or (ii) that we intend to continue with such development notwithstanding the non-achievement of such Successful Completion, or the Licensor Continuation Notice. Also, in the event that we do not achieve the Successful Completion of the potential Phase 3 Study, we shall, as soon as practicable, notify Samil accordingly, or the Notice of Non-Success. Samil shall thereafter have the option, by notice in writing served to us within 45 days of Samil's receipt of either a Cessation Notice, a Licensor Continuation Notice or a Notice of Non-Success, as applicable, to indicate its intention either: (i) to terminate the Samil License, or (ii) to continue research and development of the Licensed Information in the Field of Use in the Territory, or the Licensee Continuation Notice. In the event Samil shall serve a Licensee Continuation Notice following the service of a Cessation Notice or a Notice of Non-Success, any such continuation by Samil shall be subject to the entry by Samil into a written agreement with us as to the terms and conditions which would govern such continued research and development, which would be carried out according to Samil's own development plan and at its sole expense. In the event Samil serves a Licensee Continuation Notice following the service of a Licensor Continuation Notice, or Agreed Continuation, the Samil Agreement shall continue in accordance with its terms. In August 2018, Samil sent a Licensee Continuation Notice to us.

Additionally, following the Successful Completion of the ARREST Study or Agreed Continuation following non-achievement of Successful Completion of the ARREST Study, Samil shall, for a period of 90 days following the

date of written notification to it by us of such Successful Completion or following the date of Agreed Continuation following non-achievement of Successful Completion, have the option to require that the Territory be extended to include Vietnam, or the Extension Option. In the event that Samil exercises its Extension Option, the parties shall conduct negotiations in good faith for up to 30 days thereafter in order to agree on milestone payments which would replace those set out in the Samil Agreement. In the event that agreement is not reached in such regard within such period, the Extension Option shall terminate. Discussions for the extension of the Samil License to Vietnam are ongoing.

OWL

On July 8, 2015, we entered into a Research, Option and License Agreement, or the OWL License Agreement, with OWL, for the development of a non-invasive, blood-based complimentary diagnostic tool, which we believe could increase the likelihood of success of our Phase 3 trials and facilitate the market adoption of Aramchol. Pursuant to the terms of the OWL License Agreement, we have partially funded the research and development of the diagnostic tool in the amount of Euro 437,000. Subject to development under the OWL License Agreement, we have an option to exclusively license from OWL a complimentary diagnostic tool for NASH using Aramchol, or the OWL License Agreement Option, in consideration for the payment of a 10% royalty to OWL on annual net sales of the complimentary diagnostic product, exercisable by written notice to OWL at any time during the period commencing on July 8, 2015 and ending on the earlier of (I) December 31, 2016; or (II) the completion of the ARREST Study, or the Option Period. On June 22, 2017, we entered into an amendment to the Agreement, which, inter alia, extended the Option Period until the lapse of six (6) months after the publication of the results of the ARREST Study on clinicaltrials.gov. This option expired without exercise.

In addition, if OWL develops any other complimentary diagnostic tool for NASH not using Aramchol, it will pay us 10% royalties from revenues. Concurrently with the OWL License Agreement, we have entered into a Share Purchase Agreement, or the OWL SPA, pursuant to which we undertook to invest Euro 175,000 in OWL, subject to certain specified milestones, in exchange for the issuance by OWL of such number of common shares that result from dividing our investment amount by the price per share, or the Investment. In addition, under the OWL SPA, OWL has granted us an option which will allow us to invest up to €1,000,000, or the First Option, at the higher of (i) the OWL company valuation in an equity financing (or series of related financings) of at least €1,000,000 that takes place at the same time as the exercise of the First Option; or (ii) a 15% premium to OWL's valuation in the most recent equity investments of at least €1,000,000, or the Baseline Valuation. The First Option will expire at the earlier of (i) an investment by a third party in OWL in excess of €1,000,000, or (ii) the completion of the ARREST Study in our reasonable opinion. Furthermore, we have the option to purchase additional shares up to 19.9% of OWL, or the Second Option, at the higher of (x) the OWL company valuation in an equity financing (or series of related financings) of at least €2,500,000 that takes place at the same time as the exercise of the Second Option; (y) at a 15% premium to OWL's valuation in the most recent equity investment of at least €2,500,000; or (z) the Baseline Valuation. The Second Option will expire at the earlier of (A) the completion of a third party investment in OWL in excess of €2,500,000, or (B) one year following the successful completion of the ARREST Study in our reasonable opinion. Moreover, pursuant to the OWL SPA, in the event OWL issues new common shares or securities convertible into common shares, except in the event of customary curve outs, or the New Securities, we have an option to purchase up to our pro-rata share of the New Securities for the price and on the same terms as the most senior class of participating shareholders, upon our notification to OWL within 21 days of OWL's notification of their intention to issue New Securities, or the Preemptive Right. This Preemptive Right shall survive termination of the OWL SPA, provided that either the Investment or the exercise of the First option or the Second Option has taken place.

Upon exercise of the OWL License Agreement Option, we will own all rights, title and interest in and to (i) the complimentary diagnostic tool for NASH using Aramchol, excluding serum and plasma markers developed by OWL using proprietary methods and any of the OWL patents, OWL's know-how, and any other results of whatsoever nature, which are discovered, developed or invented in the course of, or directly arising from, the performance of the Research, excluding our technology, or the Research Results, which is owned by OWL; (ii) the complimentary diagnostic tool for NASH using Aramchol intellectual property; (iii) all results and intellectual property pertaining to (a) our technology, (b) markers or other diagnostics for use in connection with liver diseases and/or cholesterol gallstones and/or any other indications utilizing Aramchol and any future synthetic fatty-acid/bile conjugates or FABACs owned by us, (c) metabolomics markers predicting therapeutics or safety response of Aramchol; or (iv) any additional markers improving NASH patient selection for treatment with Aramchol that are generated, discovered, reduced to practice and/or arising in the course of and/or from the performance of any research, services and/or development activities by or on behalf of or for us (including by OWL hereunder), excluding research results, and including any regulatory filing or approval (if any) filed or obtained by us or any of our affiliates in respect of the OWLiverGAL kit and any other product, kit, device, material, process, method, activities or service that incorporates, uses, or is reliant upon the licensed technology, or the Licensed Technology Product, and all communications with regulatory authorities, and any data, information or document covered by data protection or data exclusivity, production processes, standard operating procedures, subcontractors' information and other technical information required for the sale and/or commercialization of the Licensed Technology Products, test protocols and final reports of any testing or studies with respect to the Licensed Technology Products.

Either party may terminate the OWL License Agreement (i) upon the other party's breach if such party fails to cure such breach within 60 days after receiving written notice thereof; or (ii) upon customary events such as the granting of a winding up order or upon the appointment of a temporary or permanent liquidator or receiver if such order or act is not cancelled within 60 days. We may terminate the OWL License Agreement for any reason upon 30 days' prior written notice. Further, OWL may terminate the OWL License Agreement upon 30 days' prior written notice, in the event that within 18 months of receipt of the required regulatory approval to market and sell the first Licensed Technology Product in the U.S, there has not been a first commercial sale, unless such failure or delay is caused by (i) force majeure; or (ii) the requirements of a regulatory or other governmental authority, any contract manufacturer, or due to any market shortage; or (iii) a significant technological and/or scientific barrier.

Unipharm

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

Competition

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

Other companies, including, Intercept Pharmaceuticals, Inc. Gilead Sciences, Inc., Allergan (through its acquisition of Tobira Therapeutics Inc.) and Genfit S.A., have molecules currently in Phase 3 clinical development; Madrigal, Shire, Novartis (through the in-license of Conatus Pharmaceuticals Inc.), Cirius, Inventiva and others have molecules in Phase 2B clinical development for the treatment of NASH and the fibrosis associated therewith. There are a host of other potential competitors in earlier stages of clinical development relative to us for the treatment of NASH including, but not limited to, Galectin Therapeutics Inc., AstraZeneca, Bristol-Myers Squibb, and Novartis. In February 2019, Intercept Pharmaceuticals announced its Phase 3 results of their OCA drug for the treatment of liver fibrosis due to NASH and Intercept reported that it intends to file for regulatory approval in the U.S. and Europe in the second half of 2019. If approved, OCA will become the first approved NASH drug.

Notwithstanding the foregoing, see “Item 3. Key Information—Risk Factors—Risks Related to Our Business, Industry and Regulatory Requirements—Our market is subject to intense competition. If we are unable to compete effectively, Aramchol or any other product candidate that we develop may be rendered noncompetitive or obsolete.”

Intellectual Property and Patent Strategy

The proprietary nature of, and protection for, Aramchol or any future product candidates and our discovery programs for new indications, processes and know-how are important to our business. We own patent rights to Aramchol in various jurisdictions worldwide, including within and outside of Israel. We have sought patent protection in the United States and internationally for Aramchol and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. The term of U.S. Patent No. 7,501,403, covering the use of Aramchol for the treatment of fatty liver, has been extended due to patent term adjustments of 567 days, resulting in an effective expiration date of November 3, 2023.

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

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

The patent portfolio for Aramchol contains patents and pending patent applications directed to composition of matter, manufacturing methods and methods of use. We own six U.S. patents, and corresponding foreign patents and pending patent applications, as detailed below.

The first patent family discloses and claims FABACs, including Aramchol, as well as methods for preventing or dissolving cholesterol gallstones in bile and reducing or preventing arteriosclerosis using FABACs. This patent family includes three issued U.S. patents and an issued European patent that was validated in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland and the United Kingdom. Corresponding patents have been granted in Australia, Brazil, Canada, China, Czech Republic, Belarus, Kazakhstan, Russian Federation, Hungary, Indonesia, Japan, Korea, Mexico, New Zealand, Norway, Poland, Turkey and the Ukraine. If the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended patent term for this patent family is due to expire on March 25, 2019.

The second patent family discloses and claims additional FABACs with different conjugation moieties, as well as the use of these and the compounds disclosed in the first patent family above, including Aramchol, in the treatment of fatty liver, reduction of serum cholesterol and treatment of hyperglycemia and diabetes. This patent family includes a U.S. patent directed to the treatment of fatty liver a U.S. patent directed to reduction of serum cholesterol by administering additional forms of FABACs, and a U.S. patent (Continuation-in-Part) directed to the treatment of hyperglycemia and diabetes. This patent family also includes two European patents, one patent which was validated in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom, and the second patent which was validated in Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Spain, Sweden, Switzerland, Turkey and the United Kingdom. The family also includes patents in Australia, Canada, China, Czech Republic, Azerbaijan, Belarus, Kyrgyzstan, Kazakhstan, Russian Federation, Indonesia, Japan, Korea, Israel, Mexico, New Zealand, Norway, Poland, Hungary and the Ukraine. A foreign patent application is pending in the Czech Republic. If the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended patent term for this patent family is due to expire on April 15, 2022, with the exception of the Israeli patent, which is due to expire on April 17, 2021. The terms of the U.S. patents in this family have been extended due to patent term adjustments of 567 days for U.S. Patent 7,501,403, which is directed to the treatment of fatty liver, and 24 days for U.S. Patent 8,110,564, which is directed to reduction of serum cholesterol, and 356 days for U.S. Patent 8,975,246, which is directed to disorders associated with altered glucose metabolism or insulin action.

A third patent family discloses the use of FABACs in the treatment, prevention and inhibition of progression of Alzheimer's Disease, cerebral amyloid angiopathy and other brain diseases characterized by amyloid plaque deposits. This patent family includes an issued European patent that was validated in France, Germany, Switzerland and the United Kingdom. If the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended term for this patent family is due to expire on February 1, 2030.

A fourth patent family, including pending U.S. and allowed applications in Europe directed to topical uses of FABAC compounds (anti-acne). If granted and the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended term for this patent family not including PTA and PTE is due to expire on August 7, 2034.

A fifth patent family discloses and claims second generation FABAC salt compounds. This patent family includes a pending U.S. application and allowed European application, as well as, foreign patent applications in Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan and Korea. If granted and the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended term for this patent family is due to expire on December 4, 2034.

A sixth patent family having one U.S. patent application, discloses and claims compositions comprising low doses of the second generation FABAC compounds. If granted and the appropriate maintenance, renewal, annuity or other governmental fees are paid, he non-extended term for this patent family is due to expire on June 8, 2036.

A seventh family is directed to treatment for modulating gut microbiota using Aramchol This patent family includes a pending U.S. application as well as foreign patent applications in Brazil, Canada, China, Europe, Israel, Japan and Mexico. If granted and the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended term for this patent family is due to expire on January 19, 2037.

An eighth family and a ninth family, both having PCT International Applications filed in 2017 and two pending US applications, are directed to uses of Aramchol for treating and inhibiting fibrosis. The two PCT Applications will enter National Phase by May 2019. If granted and the appropriate maintenance, renewal, annuity or other governmental fees are paid, the non-extended term of this patent family is due to expire on November 10, 2037. In addition, a US Continuation-in-part claiming priority to all of the above applications was filed in November 2018 and claims the treatment and inhibition of fibrosis by a regimen of 300 mg of Aramchol twice daily. The improved bio-availability of Aramchol is supported by the pharmacological model based on the preclinical and the ARREST data.

Combination therapy for treating fatty liver disease is covered by two US provisional patent applications: (i) directed to a combination therapy of angiotensin II type 1 receptor blocker (ARB) with S-adenosyl-L-methionine, and (ii) a US

provisional application directed to combination of FABAC and at least one thyroid hormone receptor agonist or thyroid hormone. The patent term for this patent family not including PTA and PTE is due to expire on April 12, 2039.

It is possible that the term of the patents issued in the United States within our first patent family, which includes the composition of matter patents, may be extended up to five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, (the longest possible extended patent term being five years from November 3, 2023). Patent term extension or supplementary protection certificates may be available in certain foreign countries upon regulatory approval. Independent of patent term extensions, five years of data exclusivity will be provided for this patent in the United States automatically from the day Aramchol receives regulatory approval, if it is approved, in the United States. The data exclusivity is solely for the indication tested, in this case presumably NASH. If we pursue commercialization of Aramchol in other jurisdictions, longer periods of data exclusivity of up to 11 years based on the EU "Bolar Scheme" may apply.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We believe that our patents provide broad and comprehensive coverage for the use of Aramchol for the treatment of certain liver diseases and other metabolic diseases. However, the patent positions of biopharmaceutical companies, such as ourselves, are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for the technology will depend on our success in obtaining effective claims and enforcing those claims once granted. There is no certainty that any of the Company’s pending patent applications will result in the issuance of any patents. The issued patents and those that may be issued in the future, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued or future patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of such patent. For more risks associated with the protection of our licensed intellectual property, see “Item 3. Key Information—Risk Factors—Risks Related to Our Intellectual Property.”

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or others.

Seasonality

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

Raw Materials and Suppliers

We believe that the raw materials that we require to manufacture Aramchol are readily available commodities commonly used in the pharmaceutical industry.

Manufacturing

We do not own or operate manufacturing facilities for the production of Aramchol or any future product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, API and finished product for our non-clinical research and clinical trials. We do not have long term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of Aramchol if it is approved. If Aramchol or any future product candidates are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer or collaboration partner and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to

manage our manufacturing contractors. The relevant manufacturers of our drug substance and drug products for our current pre-clinical and clinical trials have advised us that they are compliant with both cGMP and, cGLP.

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

Contract Research Organizations

We outsource certain clinical trial activities to CROs. Our clinical CROs comply with guidelines from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which attempt to harmonize the FDA, the EMA, and the Pharmaceuticals and Medical Devices Agency of Japan regulations and guidelines. We create and implement the drug development plans and manage the CROs according to the specific requirements of the drug candidate under development. To the extent clinical research is overseen by the CROs (or directly by us), compliance with certain federal regulations, including but not limited to 21 C.F.R. parts 50, 54, 56, 58 and 312, which pertain to, among other things, IRBs, informed consent, financial conflicts of interest by investigators, correct administration of treatment, follow up of adverse events, good laboratory practices and submitting IND applications, may be required.

Marketing, Sales and Commercialization

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure or capabilities. In the event we receive regulatory approval for Aramchol, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market and/or sell Aramchol or any future product candidates, if any, through their well-developed sales, marketing and distribution organizations in order to gain access to global markets. In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop. Over the longer term, we may consider ultimately building an internal marketing, sales and commercial infrastructure. See “Item 4. Information on the Company—Business Overview—Strategic Collaborations, Research Arrangements and other Material Agreements—Samil Pharm Co.” for information regarding the license agreement we entered with Samil for the commercialization of Aramchol (with an option to manufacture) for the treatment of fatty liver indications including NASH, in the Republic of Korea.

Environmental Matters

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

Government Regulation and Product Approval

Governmental authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Aramchol or any future product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the Committee on Human Medicinal Products, or CHMP, via the EMA and European Commission through the MAA process before they may be legally marketed in Europe. Aramchol or any future product candidates

will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

We are conducting a global development program for Aramchol for the treatment of NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus, and we may make our submissions for regulatory approval in parallel; initially in Europe and in the United States. Typically, approval time in the United States with the FDA for an NDA is faster than that within Europe with the EMA and the European Commission for an MAA, especially when the novelty of the submission is considered. First in class, high medical need and rare disease drugs can experience faster review. Nevertheless, marketing and pricing approval presents a further delay in many countries that should be considered in addition to the regulatory approvals noted above.

United States Government Regulation

NDA Approval Processes

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

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

- completion of pre-clinical laboratory tests, animal studies and formulation studies conducted according to GLPs, or other applicable regulations;

- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA inspections of clinical sites and GLP toxicology studies; and
- FDA review and approval of the NDA.

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

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

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with the FDA's GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an IRB must review and approve the plan for any clinical trial, including the informed consent document, before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the investigator brochure and other information about the trial distributed by the sponsor and the consent form that must be provided to each trial subject or his or her legal representative and must monitor the study until

completed. All clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject inclusion and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report within set timeframes to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in-vitro testing that suggest a significant risk in humans exposed to the drug. Sponsors must also report to FDA certain amendments to the protocol and other essential information concerning the IND that does not fall within the scope of other required reports.

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

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

- *Phase 2*. Clinical trials are performed on a limited patient population intended to identify possible adverse effects and risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. Phase 3 clinical trials are conducted to provide sufficient data for the statistically valid evidence of safety and efficacy.

- *Phase 4*. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase 4 studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase 4 studies usually involve thousands of participants. Phase 4 studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug.

Human clinical trials are inherently uncertain and Phase 1, Phase 2, Phase 3 and Phase 4 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points are typically prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may also be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the NDA. If a Phase 2 clinical trial is the subject of discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or the SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and size that will form the primary basis for the demonstration of effectiveness in a marketing application.

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

Concurrent with clinical trials, sponsors usually complete any remaining animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

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

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

Expedited Review and Approval

NDAs receive either standard or expedited review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive expedited review. The FDA has various specific programs, including Fast Track, Breakthrough Therapy, Priority Review, and Accelerated Approval, which, in different ways, are each intended to expedite the process for reviewing and approving drugs. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs, and Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track, Breakthrough Therapy designation and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track or Breakthrough Therapy designated drug and expedite review of the application for a drug designated for priority review. The FDA will also provide Breakthrough Therapy designated drugs intensive guidance on an efficient drug development program and provide these drug developers with an organizational commitment from the FDA involving senior managers. Since sponsors can design clinical trials in a number of ways, in providing its guidance for drugs designated as breakthrough therapies, the FDA will seek to ensure that the sponsor of the product designated as a breakthrough therapy receives timely advice and interactive communications in order to help the sponsor design and conduct a development program as efficiently as possible. During these interactions, the FDA may suggest, or a sponsor can propose, alternative clinical trial designs (e.g., adaptive designs, an enrichment strategy, use of historical controls) that may result in smaller trials or more efficient trials that require less time to complete. Such trial designs could also help minimize the number of patients exposed to a potentially less efficacious treatment (i.e., the control group treated with available therapy). On September 23, 2014, the FDA granted Fast Track designation status to Aramchol for the treatment of patients who are overweight or obese and have pre diabetes or type II diabetes mellitus with NASH.

Accelerated Approval, which is described in 21 C.F.R. § 314.500 *et seq*., provides for approval of a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. To be used in accelerated approval, a surrogate endpoint must be “reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence to predict benefit on irreversible morbidity or mortality.” The term “reasonably likely” implies that some uncertainty remains about the relationship of the surrogate to the clinical benefit to the patient. Therefore, accelerated approval is typically contingent on a sponsor’s agreement to conduct additional post-approval studies to verify and describe the drug’s clinical benefit. Accelerated Approval does not change the standards for approval, but by allowing a demonstration of efficacy based on a surrogate endpoint may expedite the approval process.

In 2016, the U.S. Congress enacted the 21st Century Cures Act. The law contains several provisions aimed at accelerating drug approval. In particular, it directs FDA to implement a formal review pathway to qualify biomarkers and other drug development tools. It is unclear when this new pathway will be implemented or whether using this pathway would have any impact on our clinical program.

Recent FDA Guidance

In December 2018, the FDA issued the December Guidance. The December Guidance is intended to assist sponsors in the clinical development of drugs for the treatment of noncirrhotic NASH with liver fibrosis, describes the FDA's current thinking regarding the necessary components of a drug development program for noncirrhotic NASH with liver fibrosis and identifies knowledge gaps that represent important challenges in the development of drugs for the indication. According to the FDA, the ultimate goal of NASH treatment is to slow the progress of, halt, or reverse disease progression and improve clinical outcomes (i.e., prevent progression to cirrhosis and cirrhosis complications, reduce the need for liver transplantation, and improve survival). Because of the slow progression of NASH and the time required to conduct a trial that would evaluate clinical endpoints such as progression to cirrhosis or survival, the FDA recommends sponsors consider the following liver histological improvements as endpoints reasonably likely to predict clinical benefit to support accelerated approval under the regulations:

- Resolution of steatohepatitis on overall histopathological reading and no worsening of liver fibrosis on NASH CRN fibrosis score. Resolution of steatohepatitis is defined as absent fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS score of 0–1 for inflammation, 0 for ballooning, and any value for steatosis; or

- Improvement in liver fibrosis greater than or equal to one stage (NASH CRN fibrosis score) and no worsening of steatohepatitis (defined as no increase in NAS for ballooning, inflammation, or steatosis)

Further, according the FDA, for NASH drugs approved on the basis of liver histology under the accelerated approval pathway, randomized, double-blind, placebo-controlled clinical trials designed to describe and verify the drug's clinical benefit should be underway at the time of submission of the marketing application. Clinical benefit can be verified by demonstrating superiority to placebo in delaying disease progression measured by a composite endpoint.

The EMA also recently issued a reflection paper to provide guidance on drug development in the field of NASH. However, the EMA indicated, among other things, that both resolution of NASH without worsening of fibrosis and improvement in fibrosis without worsening of NASH would both be required as intermediate endpoints for demonstrating statistical significance for stage 2 and 3 fibrosis.

Patent Term Restoration and Marketing Exclusivity

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

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

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

Post-approval Requirements

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

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

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

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

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be. In particular, it is unknown whether any of the provisions of the 2016 21st Century Cures Act that are intended to accelerate drug approval will result in any change in the current approval pathway for Aramchol.

Pursuant to the Affordable Care Act (discussed in greater detail below), the Centers for Medicare & Medicaid Services (CMS) is required to collect and publish information reported by applicable manufacturers about payments and other transfers of value manufacturers have made to physicians and teaching hospitals. Such a law, when applicable to our products, could increase the company's regulatory liability through the imposition of additional reporting and regulatory requirements. There are also an increasing number of state laws that require manufacturers to make similar reports to states on pricing and marketing information.

Reimbursement

We face uncertainties over the pricing of pharmaceutical products. Sales of Aramchol or any future product candidates will depend, in part, on the extent to which the costs of Aramchol or any future product candidates will be covered by third-party payors, such as federal health programs, commercial insurance and managed care organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, foreign governments and third party payors have shown significant interest in implementing cost-containment programs, including price controls, pricing transparency disclosure obligations, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider Aramchol or any future product candidates to be cost-effective compared to other therapies, they may not cover Aramchol or any future product candidates after approved as a benefit under their plans or, if they do, the level

of payment may not be sufficient to allow us to sell Aramchol or any future product candidates on a profitable basis.

The Medicare Modernization Act imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries under Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. The Centers for Medicare & Medicaid Services published a final rule in 2014 implementing the Medicare Modernization Act. Contrary to the proposed rule, which would have enabled Part D plans to offer fewer drugs, the final rule maintained the existing six protected classes of drug categories, but stated that some of the proposals not included in the final rule could still be finalized in the future, which would impact payor formulary and coverage decisions.

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

The Affordable Care Act, enacted in March 2010, has had a significant impact on the health care industry. Some of the key changes made to date pursuant to the Affordable Care Act include an expansion of coverage for the uninsured, the creation of insurance marketplaces and increased protection of insureds with new benefits, rights and protections. With regard to pharmaceutical products, among other things, the Affordable Care Act made major changes to the Medicare prescription drug program, which helped reduce drug costs for seniors and increased rebates and other costs for the pharmaceutical industry.

On January 20, 2017, President Donald J. Trump was inaugurated as the President of the United States. President Trump has stated that he intends to "repeal and replace" the Affordable Care Act, and Congress has taken initial steps to repeal the law. In December 2017, Congress passed and the President signed into law tax reform legislation that made significant changes to the Affordable Care Act including the repeal of the "individual mandate" that was in place to strongly encourage broad participation in the health insurance markets. . On December 14, 2018, a federal district court in Texas ruled that the PPACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the PPACA. The case, Texas, et al, v. United States of America, et al., (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge. We are not able to state with any certainty what will be impact of this court decision on our business pending further court action and possible appeals. Given these changes and other statements of political leaders, we cannot predict the ultimate impact on the Affordable Care Act and the subsequent effect on the pharmaceutical industry at this time

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for Aramchol or any future product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Healthcare Fraud and Abuse Laws

In the U.S., the research, development, testing, manufacturing, handling, storage, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the fraud and abuse provisions applicable to pharmaceutical manufacturers, including the federal "Anti-Kickback Statute", the Civil Monetary Penalty Statute, the Stark Law, the federal False Claims Act, as

amended, state and federal “Physician Payment Sunshine Act” laws and regulations, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Anti- Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.

The federal False Claims Act prohibits anyone from knowingly presenting, conspiring to present, making a false statement in order to present, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This law also prohibits anyone from knowingly underpaying an obligation owed to a federal program. Increasingly, U.S. federal agencies are requiring nonmonetary remedial measures, such as corporate integrity agreements in False Claims Act settlements. The U.S. Department of Justice announced in 2016 its intent to follow the “Yates Memo,” taking a far more aggressive approach in pursuing individuals as False Claims Act defendants in addition to the corporations.

The Physician Payment Sunshine Act, enacted in 2010 as part of the Affordable Care Act, requires manufacturers of pharmaceuticals and medical devices to annually report certain payments and other transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. In recent years, several states in the United States have also enacted legislation requiring pharmaceutical companies to file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as establish marketing compliance programs. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. Failure to meet these requirements, to the extent they are applicable to our activities, also could result in a variety of governmental sanctions that could have a material adverse effect on our business.

European Economic Area

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

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

Centralized Procedure

Regulation 726/2004/EC governs the centralized procedure when a marketing authorization is granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the EMA. That authorization is valid throughout the entire community and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of certain biotechnological processes in accordance with Paragraph 1 to the Annex to the Regulation. Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes, autoimmune diseases and other immune dysfunctions and viral diseases must also be authorized centrally. Finally, all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000 and Advanced Therapy Medicinal

Products (ATMP) according to Reg. (EC) No. 1394/2007 and medicinal products for veterinary use that are used primarily as performance enhancers must be authorized under the centralized procedure. An applicant may also opt for assessment through the centralized procedure if the medicinal product contains a new active substance which was not authorized in the EU when Reg. (EC) No. 726/2004 entered into force, or if the applicant can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients or animal health at the community level. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application. This 210 days period does not include the time that the applicant needs to answer any questions raised during the application procedure, the so-called 'clock stop' period. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the draft decision granting a marketing authorization. This draft decision may differ from the CHMP opinion, stating reasons for diverging from the CHMP opinion. The draft decision is sent to the applicant and the member states, after which the European Commission takes a final decision. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. All CHMP refusals and the reasons for refusal are made public on the EMA website. Without a centralized marketing authorization it is prohibited to place a medicinal product that must be authorized centrally on the market in the EU. Once a centralized marketing authorization has been granted by the European Commission, it is valid in all EEA States for 5 years on a renewable basis.

Mutual Recognition and Decentralized Procedures

With the exception of products that are authorized centrally, the competent authorities of the member states are responsible for granting marketing authorizations for medicinal products placed on their national markets. If the applicant for a marketing authorization intends to market the same medicinal product in more than one member state, the applicant may seek an authorization progressively in the community under the mutual recognition or decentralized procedure. Mutual recognition procedure, or MRP is used if the medicinal product has already been authorized in a member state. In this case, the holder of this marketing authorization requests the member state where the authorization has been granted to act as reference member state by preparing an updated assessment report that is then used to facilitate mutual recognition of the existing authorization in the other member states in which approval is sought (the so-called concerned member state(s)). The reference member state must prepare an updated assessment report within 90 days of receipt of a valid application. This report together with the approved Summary of Product Characteristics, the SmPC (which sets out the conditions of use of the product), and a labeling and package leaflet are sent to the concerned member states for their consideration. The concerned member states are required to approve the assessment report, the SmPC and the labeling and package leaflet within 90 days of receipt of these documents. The total procedural time of the MRP is 180 days.

The decentralized procedure, or DCP is used in cases where the medicinal product has not received a marketing authorization in the EU at the time of application. The applicant requests a member state of its choice to act as reference member state to prepare an assessment report that is then used to facilitate agreement with the concerned member states and the grant of a national marketing authorization in all of these member states. In this procedure, the reference member state must prepare, for consideration by the concerned member states, the draft assessment report, a draft SmPC and a draft of the labeling and package leaflet within 120 days after receipt of a valid application. As in the case of mutual recognition, the concerned member states are required to approve these documents within 90 days of their receipt, i.e. the total time of the DCP is 210 days.

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

Irrespective of whether the medicinal product is assessed centrally, de-centrally or through a process of mutual recognition, the medicinal product must be manufactured in accordance with the principles of GMP as set out in Directive2001/83/EC and Directive 2003/94/EC, or, Directive 2017/1572/EU that will replace Directive 2003/94/EC expectedly by 2019.

Directive 2003/94/EC and Volume 4 of the rules governing medicinal products govern GMP in the European community. Moreover, community law requires the clinical results in support of clinical safety and efficacy based upon clinical trials conducted in the European community to be in compliance with the requirements of Directive 2001/20/EC, which implements good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the European community and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the community. Directive 2001/20/EC will be replaced by Regulation (EU) No. 536/2014 on Clinical Trials in the near future. Although the Regulation entered into force on 16 June 2014, the timing of its application depends on the development of a fully functional EU clinical trials portal and database, which will be confirmed by an independent audit. The Regulation becomes applicable six months after the European Commission publishes a notice of this confirmation. The entry into application of the Regulation is currently estimated to occur in 2019. Once the new Regulation becomes applicable, clinical trials law in the EU will be further harmonized.

National Procedure

This procedure is available for medicinal products that do not fall within the scope of mandatory centralized authorization. Specific procedures and timelines differ between member states, but the duration of the procedure without clock-stop time is generally 210 days and based on a risk/efficacy assessment by the competent authority of the member state concerned, followed by determination of SmPC, package leaflet and label text/layout and subsequently grant of the marketing authorization. Marketing authorizations granted on this basis are not mutually recognized by other member states, but the national marketing authorization can later be used in an MRP to obtain marketing authorizations in other member states.

There are various types of applications for marketing authorizations:

- *Full Applications*. A full application is one that is made under any of the community procedures described above and that "stands alone" in the sense that it contains all of the particulars and information required by Article 8(3) of Directive 2001/83 (as amended) to allow the competent authority to assess the quality, safety and efficacy of the product and in particular the balance between benefit and risk. Article 8(3)(l) in particular refers to the need to present the results of the applicant's research on (i) pharmaceutical (physical-chemical, biological or microbiological) tests, (ii) pre-clinical (toxicological and pharmacological) studies and (iii) clinical trials in humans. The nature of these tests, studies and trials is explained in more detail in Annex I to Directive 2001/83/EC. Full applications would be required for products containing new active substances not previously approved by the competent authority, but may also be made for other products.

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

Cross-referral to Innovator's Data

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

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

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

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

Well-established Medicinal Use

Under Article 10a of Directive 2001/83/EC, an applicant may, in substitution for the results of its own pre-clinical and clinical research, present detailed references to published literature demonstrating that the active substance(s) of a product have a well- established medicinal use within the community for at least ten years with recognized efficacy and an acceptable level of safety in terms of the conditions set out in Annex I of Directive 2001/83/EC. In that event, the test and trial results shall be replaced by appropriate scientific literature. The applicant is entitled to refer to a variety of different types of literature, including reports of clinical trials with the same active substance(s) and epidemiological studies that indicate that the constituent or constituents of the product have an acceptable safety/efficacy profile for a particular indication. However, use of the published literature exemption is restricted by stating that in no circumstances active substances be treated as having a well- established use if they have been used for less than 10 years from the first systematic and documented use of the substance as a medicinal product in the EU. Even after 10 years' systematic use, the threshold for well-established medicinal use might not be met. European pharmaceutical law requires the competent authorities to consider among other factors the period over which a substance has been used, the amount of patient use of the substance, the degree of scientific interest in the use of the substance (as reflected in the scientific literature) and the coherence (consistency) of all the scientific assessments made in the literature. For this reason, different substances may reach the threshold for well-established use after different periods, but the minimum period is 10 years. If the applicant seeks approval of an entirely new therapeutic use compared with that to which the published literature refers, additional pre-clinical and/or clinical results would have to be provided.

Authorization Holder's Consent

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

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) was adopted on December 12, 2006. This Regulation governs the development of medicinal products for human use in order to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a product not authorized in the European Community on January 26, 2007 (the time the Regulation entered into force), to include the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed by the Pediatric Committee of the EMA, unless the product is subject to an agreed waiver or deferral or unless the product is excluded from the scope of Regulation 1901/2006 (generics, hybrid medicinal products, biosimilars, homeopathic and traditional (herbal) medicinal products and medicinal products containing one or more active substances of well-established medicinal use) according to its Art. 9. Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. The EMA does not evaluate an application for market authorization that is not exempt from Regulation (EC) 1901/2006 if there is no agreed PIP, deferral or waiver. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a product already authorized and still protected by a supplementary protection certificate granted under Regulation EC 469/2009 and its precursor Regulation (EEC) 1768/92 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation (EC) 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the product, unless the product is subject to orphan drug designation, in which case the 10-year market exclusivity period for such an orphan product is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six month extension of the supplementary protection certificate is only granted if the medicinal product is authorized in all member states.

Post-authorization Obligations

In the pre-authorization phase, the applicant must provide a detailed pharmacovigilance plan that it intends to implement post- authorization. An authorization to market a medicinal product in the EU carries with it an obligation to comply with many post- authorization organizational and behavioral regulations relating to the marketing and other activities of authorization holders. These include requirements relating to post-authorization efficacy studies, post-authorization safety studies, adverse event reporting and other pharmacovigilance requirements, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers. EU pharmacovigilance legislation has been significantly modified by the Pharmacovigilance Directive, Dir. 2010/84/EU which amended the legal framework of pharmacovigilance for medicines marketed within the EU provided in Regulation (EC) No 726/2004 with respect to EU authorized medicinal products and in Directive 2001/83/EC with respect to nationally authorized medicinal products (including those authorized through the mutual recognition and decentralized systems). In addition, Commission Implementing Regulation (EU) No 520/2012 outlines the practical details to be respected by marketing authorization holders, national competent authorities and the EMA, and Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Furthermore, EU good pharmacovigilance practice (GPC) rules apply. With the amended pharmacovigilance requirements, the financial and organizational burden on market authorization holders increased significantly, such as the obligation to maintain a pharmacovigilance system master file that applies to all holders of marketing authorizations granted in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. Marketing authorization holders must furthermore collect data on adverse events associated with use of the authorized product outside the scope of the authorization. Pharmacovigilance for biological products and medicines with a new active substance is strengthened by subjecting their authorization to additional monitoring activities.

Any authorization granted by member state authorities, which within three years of its granting is not followed by the actual placing on the market of the authorized product in the authorizing member state, ceases to be valid (Art. 24 (4) and (5) Directive 2001/83/EC). When an authorized product previously placed on the market in the authorizing member state is no longer actually present on the market for a period of three consecutive years, the authorization for that product shall cease to be valid. The same two three year periods apply to authorizations granted by the European Commission based on the centralized procedure (Art. 14 (4) and (5) Regulation (EC) 726/2004).

Other Countries

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

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

Related Matters

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

C. Organizational Structure

See “Item 4. Information on the Company—Historical Background and Corporate Structure” above.

D. Description of Property and Facilities

Our corporate headquarters are located at 16 Tiomkin Street, Tel Aviv, pursuant to a lease to occupy approximately 356 square meters of space. On March 22, 2015, GRD entered into the lease agreement with Mintz K. Construction Company for the corporate headquarters. The term of the lease is for four years with an option, at the election of GRD, for two additional years. The aggregate quarterly rental payment for four years, together with adjustments and the maintenance fees, is approximately NIS 33,055 plus VAT. On February 27, 2017, GRD entered into an addendum to the lease agreement pursuant to which GRD leased an additional 90 square meters for a space adjacent to the current premises, totaling 446 square meters. The fees for the additional space are payable quarterly in an aggregate amount of NIS 17,700 plus VAT. On August 9, 2018, GRD entered into an additional addendum to the lease agreement pursuant to which GRD leased an additional 144 square meters for a space adjacent to the current premises and provided for an additional option to extend the lease for two additional periods of one year each. The fees for the additional space are payable quarterly in an aggregate amount of NIS 28,800 plus VAT. On November 28, 2018, GRD exercised its option to extend for a further two years. The total quarterly fees for the total 590 square meters are NIS 98,037 plus VAT and as of March 22, 2019 will increase to NIS 119,271 plus VAT.

ITEM 4A. Unresolved Staff Comments.

Not applicable.

ITEM 5. Operating and Financial Review and Prospects.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Item 3. Key Information—Selected Financial Data" above and our financial statements and related notes that appear elsewhere in this annual report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in the sections titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on the development of Aramchol, a liver targeted stearoyl-coenzyme A desaturase-1, or SCD1, modulator, first in class, novel, oral therapy for the treatment of NASH for variable populations. In June 2018, we announced top line data from our ARREST Phase 2b clinical study, a multicenter, randomized, double blind, placebo-controlled study, designed to evaluate the efficacy and safety of Aramchol in 247 subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. We are currently focused on preparing for an end of Phase 2b meeting with the FDA to discuss the results of the ARREST Study and a proposed Phase 3/4 study protocol for the pivotal ARMOR Study, with a view to initiating the ARMOR Study at the end of the second quarter or early in the third quarter of 2019.

To date, we have not generated revenue from the sale of any product, excluding the licensing revenue we recorded in connection with the Samil Agreement, and we do not expect to generate any significant revenue other than the amortization of the upfront payments under the license agreement with Samil and of the subsequent royalties and/or milestones that may be earned in connection with the Samil Agreement or potential other license Agreements, unless and until we commercialize Aramchol, or license the product to additional third parties. As of December 31, 2018, the Company had an accumulated deficit of approximately $86.5 million.

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

Financial Overview

To date, we have funded our operations primarily through proceeds from private placements and public offerings. At December 31, 2018, we had current assets $90.4 million, which is mainly comprised of cash and cash equivalents of $24.2 million, short-term deposits of $6.1 million and short-term investment securities of $60.0 million. This compares with current assets of $19.2 million at December 31, 2017, which is mainly comprised of cash and cash equivalents of $13.0 million and short-term investment securities of $6.0 million. We believe that such existing funds will be sufficient to continue our business and operations as currently conducted for more than 12 months from the date of issuance of this annual report. However, we will continue to incur operating losses, which may be substantial over the next several years, and we will need to obtain additional funds to further develop our research and development programs.

Revenues

We have entered into the Samil Agreement for the commercialization of Aramchol in Korea. Under the terms of the Samil Agreement, we have received upfront and milestone payments of $3.6 million, and may be eligible to receive up to approximately $4.5 million in additional payments for development and regulatory milestones for Aramchol in the licensed territories.

In accordance with ASC 606, we determined that the Samil Agreement included a combined performance obligation representing the delivery of the exclusive license and completion of the ARREST study.

We determined that the transaction price at contract inception was $2.1 million consisting of the upfront, non-refundable payment. None of the clinical or regulatory milestones were included in the transaction price upon inception, as all milestone amounts were fully constrained. Management assessed that the likelihood of occurrence of the other performance obligations in the Samil Agreement was remote upon contract inception. As such, the standalone value of such performance obligations was deemed de minimis and none of the transaction price was allocated to those obligations. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, and therefore have also been excluded from the transaction price.

During 2018, when we determined that the achievement of its first milestone was probable, it included the variable consideration of $1.5 million as a part of the transaction price allocated to the combined performance obligation including the delivery of the license and completion of the ARREST study. We will re-evaluate the transaction price in each reporting period when events whose outcomes are resolved or other changes in circumstances occur that would indicate it is appropriate to recognize variable consideration as revenue.

Revenue allocated to the combined performance obligation of the license and associated ARREST study was recognized ratably, based on the input method, from contract inception through conclusion of the ARREST study in June 2018.

Costs and Operating Expenses

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

Research and Development Expenses

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

We expect that a substantial amount of our research and development expense in the future will be incurred in support of our current and anticipated pre-clinical and clinical development projects. Due to the inherently unpredictable nature of pre-clinical and clinical development studies, we are unable to estimate with any certainty the costs we will incur in the continued development of Aramchol for NASH and other indications in our pipeline for potential partnering and/or commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We currently expect to continue testing Aramchol in pre-clinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for Aramchol.

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

We expect our research and development expenses to increase in the future from current levels as we continue to advance of our clinical product development into a pivotal stage trial and, potentially, the in-licensing of additional product candidates.

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

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational roles, including finance/accounting, legal and other operating positions in connection with our activities. Our other significant general and administrative expenses include non-cash stock-based compensation costs and facilities costs (including the rental expense for our offices in Tel Aviv, Israel), professional fees for outside accounting and legal services, travel costs, investors relations, insurance premiums and depreciation.

Financial Income, Net

Our financial income consists mainly of interest income from marketable debt securities and short-term deposits, as well as gains from realization of marketable debt securities and foreign currency gains. Our financial expense consists of fees associated with banking activities and losses from realization of marketable debt securities.

Critical Accounting Policies and Estimate

We prepare our financial statements in accordance with U.S. GAAP. In doing so, we must make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. In some cases, we could reasonably have used different accounting policies and estimates. Changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. Significant estimates include, but are not limited to, those related to deferred revenue, revenue recognition and stock-based compensation. For further significant accounting policies please see Note 2 to our audited consolidated financial statements of this annual report. We believe that our accounting policies contained therein are critical in fully understanding and evaluating our financial condition and operating results.

Jumpstart Our Business Startups Act of 2012

We are an emerging growth company within the meaning of the rules under the Securities Act and we will utilize certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. We could remain an “emerging growth company” for up to five years from the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act (i.e. December 31, 2019), or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1.07 billion (as such amount is indexed for inflation every five years by the SEC to reflect the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics, setting the threshold to the nearest $1.0 million) or more, (b) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1 billion in nonconvertible debt during the preceding three year period.

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

Stock-Based Compensation and Fair Value of Ordinary Shares

We apply ASC 718-10, "Share-Based Payment," which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options under the Company's stock plans, based on estimated fair values. ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of the grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated statement of operations. The foregoing estimates of fair value that the Company has made are highly complex and subjective. The estimates of the fair value of the Company's ordinary shares will not be necessary to estimate the fair value of new awards as the shares started trading on the Nasdaq Capital Market as of March 2014.

In June 2018, we have elected to early adopt ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," which simplifies the accounting for nonemployee share-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for share-based payment awards to employees. The amendments expand the scope of the accounting standard for share-based payment awards to include share-based payment awards granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance related to equity-based payments to non-employees.

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

The valuations were performed contemporaneously with the offerings of ordinary shares to which such valuations relate. Such valuations were conducted by us and were directly observable in the marketplace. Such valuations were in accordance with the provisions of ASC 820-35 and based on the purchase price paid by new external and independent investors with pharmaceutical or financial expertise, who purchased our convertible notes contemporaneously with or around the time of our equity issuances. Increases in the Company's valuations were based upon the progress in the clinical development of Aramchol, submissions of new families of patent applications for new potential indications and new formulations of Aramchol, an investment round and our initial public offering in March 2014.

A. Results of Operations

The table below provides our results of operations (which reflect the results of operations of the Company, post reorganization, as well as the financial data of the GHI, our predecessor, prior to the Reorganization for the year ended December 31, 2018 as compared to the years ended December 31, 2017 and 2016.

	Year Ended December 31,		
	2016	2017	2018
	(thousands)		
Revenue	$467	$1,085	$2,038
Research and development expenses	14,271	9,650	8,313
General and administrative expenses	3,078	3,799	4,400
Operating loss	16,882	12,364	10,715
Financial income, net	(35)	(65)	(934)
Loss before income taxes	16,847	12,299	9,781
Income taxes	106	-	75
Net loss	$16,953	$12,299	$9,856
Comprehensive loss	$16,832	$12,221	$9,860
Basic and diluted net loss per share from continuing operations	$1.49	$0.98	$0.54

Revenue

Licensing revenue amounted to $2.0 million during the year ended December 31, 2018, compared to $1.1 million of revenue for the year ended December 31, 2017. The above-mentioned revenue resulted from the amortization of the upfront payment and a $1.5 million milestone payment received under the Samil Agreement.

Licensing revenue amounted to $1.1 million during the year ended December 31, 2017, compared to $0.5 million of revenue for the year ended December 31, 2016. The above-mentioned revenue resulted from the amortization of the upfront payments under the Samil Agreement.

Research and Development Expenses

Our research and development expenses amounted to approximately $8.3 million during the year ended December 31, 2018, representing a decrease of approximately $1.4 million, or approximately 14%, compared to approximately $9.7 million for the year ended December 31, 2017. The decrease primarily resulted from a decrease in research and development subcontractor expenses in connection with the completion of the ARREST Study of approximately $2.5 million; partially offset by an increase of approximately $0.5 million in salaries and benefits paid to new employees hired since the comparable prior year period. We expect that research and development expenses will significantly increase through 2019 and beyond.

Our research and development expenses amounted to approximately $9.7 million during the year ended December 31, 2017, representing a decrease of approximately $4.6 million, or approximately 32%, compared to approximately $14.3 million for the year ended December 31, 2016. The decrease primarily resulted from a decrease in research and development subcontractor expenses in connection with the ARREST Study of approximately $2.4 million and other studies of an aggregate of approximately $1.0 million. The decrease in the research and development expenses is also as a result of a decrease in drug development related expenses of approximately $1.0 million.

General and Administrative Expenses

Our general and administrative expenses amounted to approximately $4.4 million for the year ended December 31, 2018, representing an increase of approximately $0.6 million, or 16%, compared to approximately $3.8 million for the year ended December 31, 2017. The increase primarily resulted from an increase in non-cash stock based compensation expenses of approximately $0.4 million as well as an increase in professional services expenses of

approximately $0.3 million. We expect that general and administrative expenses will increase through 2019 and beyond.

Our general and administrative expenses amounted to approximately $3.8 million for the year ended December 31, 2017, representing an increase of approximately $0.7 million, or 23%, compared to approximately $3.1 million for the year ended December 31, 2016. The increase primarily resulted from an increase in salaries and benefits expenses of approximately $0.6 million as well as an increase in investor relations and business development expenses of approximately $0.2 million.

Operating Loss

As a result of the foregoing research and development and general and administrative expenses, as well as our failure to generate substantial operating revenues, our operating loss for the year ended December 31, 2018 was approximately $10.7 million, representing a decrease in our operating loss of approximately $1.7 million, or approximately 14%, compared to approximately $12.4 million for the year ended December 31, 2017.

Our operating loss for the year ended December 31, 2017 was approximately $12.4 million, representing a decrease in our operating loss of approximately $4.5 million, or approximately 27%, compared to approximately $16.9 million for the year ended December 31, 2016.

Financial Income, Net

Our financial income, net, for the year ended December 31, 2018 was approximately $0.9 million, representing an increase of approximately $0.8 million, or approximately 800%, compared to approximately $0.1 million for the year ended December 31, 2017. The increase primarily resulted from an increase in interest income from marketable debt securities and short-term deposits resulting from our implementation of a cash management strategy during the year in an effort to generate revenues with excess liquidity.

Our financial income, net, for the year ended December 31, 2017 was approximately $0.06 million, representing an increase of approximately $0.03 million, or approximately 86%, compared to approximately $0.035 million for the year ended December 31, 2016.

Net Loss

Our net loss for the year ended December 31, 2018 was approximately $9.9 million, representing a decrease of approximately $2.4 million, or approximately 20%, compared to approximately $12.3 million for the year ended December 31, 2017. The decrease primarily resulted from the above-mentioned decrease in research and development expenses and as well the increase in revenues due to the milestone payment received from Samil.

Our net loss for the year ended December 31, 2017 was approximately $12.3 million, representing a decrease of approximately $4.7 million, or approximately 27%, compared to approximately $17.0 million for the year ended December 31, 2016. The decrease primarily resulted from the above-mentioned decrease in research and development expenses.

B. Liquidity and Capital Resources

Overview

To date, we have funded our operations primarily through proceeds from private placements and public offerings. During the year ended December 31, 2018, we raised $70.3 million in net proceeds in an underwritten public offering that was completed in June 2018, $5.9 million in net proceeds in a registered direct offering during April 2018 and $2.9 from our existing ATM Offering. Under our existing ATM Offering, as of December 31, 2018, we may sell, from time to time, up to approximately $32.0 million of additional ordinary shares.

We have incurred substantial losses since our inception. As of December 31, 2018, we had an accumulated deficit of approximately $86.5 million and working capital (current assets less current liabilities) of approximately $87.7 million. Due to our expectation that we will continue to not generate substantial revenues for the foreseeable future, we expect that losses will continue for the foreseeable future.

As of December 31, 2018, we had cash and cash equivalents of approximately $24.2 million, short-term deposits of approximately $6.0 million and marketable debt securities of approximately $60.0 million invested in accordance with our investment policy, totaling approximately $90.2 in highly-liquid assets, as compared to cash and cash equivalents of approximately $13.0 million and marketable debt securities of approximately $6.0 million invested in accordance with our investment policy, totaling approximately $19.0 in highly-liquid assets as of December 31, 2017. The increase is mainly attributable to the approximately $70.3 million in net proceeds raised in an underwritten public offering that was completed in June 2018, together with $5.9 million in net proceeds raised in a registered direct

offering during April 2018.

As of December 31, 2017, we had cash and cash equivalents of approximately $13.0 million and marketable debt securities of approximately $6.0 million invested in accordance with our investment policy, totaling approximately $19.0 in highly-liquid assets, as compared to approximately $3.1 million and approximately $12.4 million as of December 31, 2016 totaling approximately $15.5 million in highly-liquid assets, respectively. The increase is primarily attributable to the net proceeds from our registered direct offering and concurrent private placement (approximately $2.7 million) and our existing and former ATM Offerings (approximately $12.4 million); partially offset by our net loss of approximately $12.3 million.

Cash Flow from Operating Activities

We had negative cash flow from operating activities of approximately $9.0 million for the year ended December 31, 2018 as compared to a negative cash flow from operating activities of approximately $12.1 million for the year ended December 31, 2017. The negative cash flow from operating activities for the year ended December 31, 2018 was mainly attributable to our net loss of approximately $9.9 million.

We had negative cash flow from operating activities of approximately $12.1 million for the year ended December 31, 2017 as compared to a negative cash flow from operating activities of approximately $12.1 million for the year ended December 31, 2016. The negative cash flow from operating activities for the year ended December 31, 2017 was mainly attributable to our net loss of approximately $12.3 million.

Cash Flow from Investing Activities

We had negative cash flow from investing activities of approximately $60.0 million for the year ended December 31, 2018 as compared to a positive cash flow from investing activities of approximately $6.4 million for the year ended December 31, 2017. The negative cash flow from investing activities for the year ended December 31, 2018 was mainly due to investment in marketable debt securities in the amount of approximately $92.3 million, offset by maturity of marketable debt securities in the amount of approximately $38.4 million.

We had positive cash flow from investing activities of approximately $6.4 million for the year ended December 31, 2017 as compared to a positive cash flow from investing activities of approximately $6.3 million for the year ended December 31, 2016. The positive cash flow from investing activities for the year ended December 31, 2017 was mainly due to maturity of marketable debt securities in the amount of approximately $10.3 million, offset by investment in marketable debt securities in the amount of approximately $3.9 million.

Cash Flow from Financing Activities

We had positive cash flow from financing activities of approximately $80.2 million for the year ended December 31, 2018 as compared to a positive cash flow from financing activities of $15.5 million for the year ended December 31, 2017. The positive cash flow from financing activity for the year ended December 31, 2018 was mainly due to the approximately $70.3 million in net proceeds raised in an underwritten public offering that was completed in June 2018, together with $5.9 million in net proceeds raised in a registered direct offering during April 2018 and $2.9 million in net proceeds raised under our ATM offering.

We had positive cash flow from financing activities of approximately $15.5 million for the year ended December 31, 2017 as compared to a positive cash flow from financing activities of $4.7 million for the year ended December 31, 2016. The positive cash flow from financing activity for the year ended December 31, 2017 was mainly due to the net proceeds from our registered direct offering and concurrent private placement (approximately $2.7 million and our existing and former ATM Offerings (approximately $12.4 million).

Current Outlook

Developing drugs, conducting clinical and pre-clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Based on our current operating plan, we believe that our existing cash resources will be sufficient to fund our projected cash requirements for more than 12 months from the date of issuance of this annual report.

Our future capital requirements will depend on many other factors, including:

- the progress and costs of our pre-clinical studies, clinical trials and other research and development activities;

- the scope, prioritization and number of our clinical trials and other research and development programs;

- the amount of revenues and contributions we receive under future licensing, development and commercialization arrangements with respect to Aramchol;

- the costs of the development and expansion of our operational infrastructure;

- the costs and timing of obtaining regulatory approval for Aramchol;

- the ability of us, or our collaborators, to achieve development milestones, marketing approval and other events or developments under our potential future licensing agreements;

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

- the costs and timing of securing manufacturing arrangements for clinical or commercial production;

- the costs of contracting with third parties to provide sales and marketing capabilities for us;

- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or platforms;

- the magnitude of our general and administrative expenses; and

- any cost that we may incur under future in- and out-licensing arrangements relating to Aramchol.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through the net proceeds from our initial public offering, debt or equity financings (such as the ATM Offering) or by out-licensing applications of Aramchol. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of Aramchol. This may raise substantial doubts about the Company's ability to continue as a going concern.

C. Research and Development, Patents and Licenses

For information concerning our research and development policies and a description of the amount spent during each of the last three fiscal years on company-sponsored research and development activities, see “Item 5. Operating and Financial Review and Prospects—Results of Operations.”

D. Trend Information

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

E. Off-Balance Sheet Arrangements

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

F. Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2018.

	Total	Less than 1 year	1 – 3 years
	(in thousands)		
Facility leases (1)	$ 676	$ 150	$ 526
Total	$ 676	$ 150	$ 526

(1) For a more detailed description of the facility leases, see “Description of Property and Facilities” above.

We enter into contracts in the ordinary course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice, and therefore are cancelable contracts and not included in the Contractual Obligations table above. We have included as purchase obligations our commitments under agreements to the extent they are quantifiable and are not cancelable.

Other than as described above, we 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, 2018.

ITEM 6. Directors, Senior Management and Employees.

A. Directors and Senior Management.

Set forth below is information concerning the directors, senior management and executive officers of the Company as of February 28, 2019, the latest practicable date for inclusion in this annual report. The business address for each of our directors, senior management and corporate officers is c/o Galmed Pharmaceuticals Ltd., 16 Tiomkin St., Tel Aviv 6578317, Israel.

Name	Age	Position
Allen Baharaff	54	President and Chief Executive Officer, Class II Director
Dr. Tali Gorfine	49	Chief Medical Officer
Dr. Liat Hayardeny	52	Chief Scientist Officer
Yohai Stenzler	36	Chief Financial Officer
Guy Nehemya	34	Chief Operating Officer
David Sidransky, M.D. [(1)(2)(3)(4)(5)(6)]	57	Lead Independent Director and External Director, Chairman of the R&D Committee
William Marth[(1)(2)(6)]	64	Class III Director, Chairman of our Nomination Committee
Shmuel Nir[(2)(3)(4)]	56	Class I Director
Tali Yaron-Eldar[(2)(3)(4)(5)(6)]	54	External Director; Chairman of our Audit Committee, Chairman of our Remuneration Committee
Prof. Ran Oren, M.D.	66	Class II director
Carol L. Brosgart, M.D.[(2)]	67	Class I Director
Marshall Heinberg	61	Class II Director

(1) A member of our research & development committee.

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

(3) A member of our audit committee.

(4) A member of our remuneration committee.

(5) An external director under the Companies Law, approved by our shareholders.

(6) A member of our nomination committee.

Allen Baharaff, our controlling shareholder, President and Chief Executive Officer and a member of our Board, co-founded the Group in 2000, served as the Chief Financial Officer of GHI from 2000 until January 2015, and has served as our Chief Executive Officer since January 2012 and as our President since March 2015. Previously, he held a senior executive position at Isramex Projects Ltd., an energy project financing company, and Managing Director of T+M Trusteeship & Management Services (Israel) Ltd., a subsidiary of a Swiss company providing trust and similar services. Since 2005, Mr. Baharaff serves as a Director of the Rubin Museum. Mr. Baharaff holds a Bachelor of Science degree in economics from the London School of Economics, University of London and LLB and MA degrees from Cambridge University. Since 1993, Mr. Baharaff has been a member of the Israel Bar Association.

Dr. Tali Gorfine, our Chief Medical Officer since March 15, 2017, joined the Company in May 2016 as the Company's Senior Medical Director. In her role as Senior Medical Director, Dr. Gorfine provided the Company with expertise regarding the Company's clinical development plan and was the point of contact for all medical related issues. Prior to joining the Company, Dr. Gorfine served as “Senior Clinical Program Leader” at Teva Pharmaceuticals global R&D division, where she led the product strategy and clinical development of Phase 2b and 3 assets. Dr. Gorfine holds a MD, PhD from Tel-Aviv University with a specialization in functional magnetic resonance imaging (fMRI).

Dr. Liat Hayardeny, our Chief Scientific Officer joined the Company in September 2016 bringing more than 16 years of experience in drug development at all stages as part of Teva Pharmaceuticals’ global Research and Development Division. Prior to joining Galmed, Dr. Hayardeny served as Teva’s Senior Director and Head of Research Scientific Affairs. In that capacity, Dr. Hayardeny established the scientific positioning of Teva’s innovative compounds. Additionally, Dr. Hayardeny was responsible for Teva’s relationship with institutions of higher education; managing Teva’s global research collaborations and publications. Dr. Hayardeny holds a Ph.D. from Sackler School of Medicine and an MBA from Recanati Business School at Tel Aviv University.

Yohai Stenzler, our Chief Financial Officer, has served in such capacity since February 1, 2017. Mr. Stenzler joined the Company in June 2014 as the Company's corporate controller, and later on served as the Company's Director of Finance. Mr. Stenzler has six years of financial management experience as an accountant at the real estate department at Ernst & Young LLP, where he was involved in financing, taxes, auditing, advising and accounting of public and private companies, both domestic and international. Mr. Stenzler is a certified CPA and holds a MBA in Finance from Recanati Business School at Tel Aviv University, and a BA in Economics and Accounting from Ben-Gurion University of the Negev.

Guy Nehemya, our Chief Operating Officer, has served in such capacity since March 2017. Mr. Nehemya joined the Company in October 2013 as the Company's Director of Operations, after completing his internship at Agmon, Rosenberg, HaCohen & Co. Law Offices. Mr. Nehemya was a key member of management during the Company’s initial public offering and execution thereof. Mr. Nehemya holds a LL.B. from the College of Management and is currently completing his MBA degree at the IDC Herzliya. Mr. Nehemya has been a member of the Israeli Bar Association since 2012.

David Sidransky, M.D., an external director and the chairman of our Nomination Committee, joined our Board in June 2014. Dr. Sidransky is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. He serves as the Director of the Head and Neck Cancer Research Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University. He is a Professor of Oncology, Otolaryngology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at John Hopkins University and Hospital. Dr. Sidransky has written over 500 peer-reviewed publications and has contributed to more than 60 cancer reviews and chapters. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents. He has been the recipient of many awards and honors, including the 1997 Sarstedt International prize from the German Society of Clinical Chemistry, 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians and the 2004 Hinda Rosenthal Award and 2017 Team Award presented by the American Association of Cancer Research. Dr. Sidransky has served as Vice Chairman of the Board of Directors of ImClone. He is Chairman of the Board of Advaxis Inc., and Tamir Biotechnology and is a lead director at Champions Oncology and on the board of directors of Orgenesis. He is serving and has served on scientific advisory boards of corporations and institutions, including Amgen, MedImmune, Roche and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. In addition, Dr. Sidransky served as Director of American Association for Cancer Research from 2005 to 2008. Dr. Sidransky received his B.A. from Brandeis University and his M.D. from the Baylor College of Medicine.

William Marth, a director of the Company since March 2014. Since April 2018, Mr. Marth has served as the President and Chief Executive Officer of North America and Europe for Heritage Pharma Holdings Inc., a wholly owned subsidiary of Emcure Pharmaceuticals Ltd. Mr. Marth previously served as President and Chief Executive Officer of Albany Molecular Research Inc. since January 2014 until January 2018. Previously, Mr. Marth served as a Director of Albany Molecular Research Inc. and as chairman of its board of directors from June to December 2013. Prior to this, he served as President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. in the Americas from June 2010 to November 2012 and Chief Executive Officer of Teva North America from January 2008 to June 2010 and

CEO of Teva USA from January 2005 to January 2008. In addition, Mr. Marth worked with several large equity firms providing guidance on their healthcare investments. He was a member of Teva's global executive management team from 2007 to 2012. From July 1999 to January 2002, he was the Executive Vice President and Vice President of Sales and Marketing for Teva USA. Prior to joining Teva USA, he held various positions with the Apothecon division of Bristol-Myers Squibb. Mr. Marth is a pharmacist and is currently a director at the University of Illinois at Chicago College of Pharmacy (UIC). Previously, Mr. Marth served as the Chairman of the Board of Directors of Sorrento Therapeutics from 2014 to July 2017, the Chairman of the Board of the Generic Pharmaceutical Association (GPhA) in 2008 and 2009 and the American Society for Health-System Pharmacists (ASHP) in 2010, and various boards and committees, including the University of the Sciences in Philadelphia and the Board of Ambassadors for John Hopkins' Project RESTORE. Mr. Marth earned his B.Sc. in Pharmacy from the University of Illinois in 1977 and his M.B.A. in 1989 from the Keller Graduate School of Management, DeVry University.

Shmuel Nir, a director of the Company since 2007, serves as President and Chief Executive Officer of Tushia Consulting Engineers Ltd., an investment and management services company. From January 2001 to January 2016, Mr. Nir served as Chairman of the board of directors of Matan Digital Printers Ltd. From March 1998 to January 2008, he served as President and Chief Executive Officer of Macpell Industries Ltd., a leading industrial group. Between January 1991 and March 1998, Mr. Nir was an Executive Vice President of Operations at Macpell Industries Ltd. and President and Chief Executive Officer of two of its subsidiaries, New Net Industries Ltd. and New Net Assets Ltd. Prior to January 1991, Mr. Nir had held various positions with Intel Corporation in Jerusalem, Israel and Tefen Management Consulting. Between 1999 and 2006, Mr. Nir served as managing partner at Spring Venture Capital Fund. Mr. Nir holds a B.Sc. in Industrial Engineering and Management from the Technion - Israel Institute of Technology in Haifa, which was awarded in 1989.

Tali Yaron-Eldar, an external director and the chairman of our audit committee and remuneration committee, joined our Board in March 2014. Ms. Yaron-Eldar is an Israeli attorney specializing in taxation and co-founded Yaron-Eldar, Paller, Schwartz & Co., Law Offices, in January 2013. Prior to January 2013, she was a partner at the law firm of Tadmor & Co. from March 2007 until December 2012 and a partner at the law firm of Cohen, Yaron-Eldar & Co. from 2004 until March 2007. From January 2004 until January 2008, Ms. Yaron-Eldar served as the Chief Executive Officer of Arazim Investment Company and she has also served in a variety of public positions, including as the Chief Legal Advisor of the Customs and V.A.T department of the Finance Ministry of the State of Israel from 1998 to 2001 and as the Commissioner of Income Tax and Real Property Tax Authority of the State of Israel from 2002 to 2004. Ms. Yaron-Eldar also serves as a director of a number of public companies, including Rossetta Genomics Ltd., Medtechnica Ltd., Magicjack Vocaltec Ltd., Lodgia Rotex Investments Ltd., Arko Holdings Ltd., Greenergy Renewable Energy Ltd., GO.D.M Investments Ltd., and Tadea Technological Development and Automation Ltd among others. Ms. Yaron-Eldar holds an M.B.A. specializing in finance from Tel Aviv University which was awarded in 1995 and an LL.B. from Tel Aviv University which was awarded in 1987. Ms. Yaron-Eldar is also a member of the Israeli Bar Association.

Prof. Ran Oren, M.D. joined our Board in March 2017 and has served as a member of our scientific advisory board since 2014, and as the Company's Chief Medical Officer from August 1, 2016 to March 14, 2017. Prof. Oren is a Professor of Gastroenterology & Hepatology at the Faculty of Medicine, Hebrew University of Jerusalem, Israel, and is the Head of the Institute of Gastroenterology and Liver Disease at Hadassah Medical Center, Jerusalem, Israel. In addition, Prof. Oren serves as a member of the Scientific Advisory Board of Redhill Biopharma Ltd., a member of the board of directors of the Boxenbaum – Netta Foundation Ltd. (CC), provides consultancy services to MEDecide Ltd., advises Maccabi Healthcare in the field of liver and serves at the editorial board of the official journal of the American Association for the study of liver diseases Hepatology. Prof. Oren published over the years in the fields of liver fibrosis, thyroid hormone, effect on liver diseases and hepatocyte transplantation. In recent years his main research interests are in the field of non-alcoholic fatty liver disease (NAFLD) – epidemiology, risk factors, diagnosis and treatment. Prof. Oren has received numerous academic and professional awards in his field and holds several patents related to the prevention and arresting of human liver disease. In 2000, Prof. Oren established the Liver Unit at the Tel Aviv Sourasky Medical Center, where he served as Chief of Medicine from 2008 to 2010. Prof. Oren concurrently served as the President of the Israeli Association for the Study of the Liver between 2007 and 2010.

Carol L. Brosgart, M.D. joined our Board on June 7, 2017. Dr. Brosgart served as a member of Tobira Therapeutics's Board of Directors from 2009 until it was acquired by Allergan in 2016 and on the Board of Juvaris, a vaccine company. Since January 2018, she serves on the Board of Directors of Abivax, a biotechnology company, headquartered in Paris, working on HIV Cure and inflammatory diseases. Dr. Brosgart serves as a consultant to Allergan and a number of biotechnology companies in the areas of liver diseases and infectious diseases. Dr. Brosgart currently serves on the Steering Committee of the National Viral Hepatitis Roundtable, the Executive Committee of the Forum for Collaborative Research, the Steering Committee of the HBV Cure Group at the Forum, and is on the Board of Directors of the Hepatitis B Foundation and the Northern California American Liver Foundation. She is active in the public policy arena for AASLD and IDSA/HIVMA. Dr. Brosgart served as Senior Advisor on Science and Policy to the Division of Viral Hepatitis at the CDC and to the Viral Hepatitis Action Coalition at the CDC Foundation from 2011 to 2013. Dr. Brosgart has also served as a member of the clinical faculty of the School of Medicine at the University of California, San Francisco for the past four decades, where she is a Clinical Professor of Medicine, Biostatistics and Epidemiology in the Division of Global Health and Infectious Diseases. In 2011, Dr.

Brosgart served as Chief Medical Officer at biotechnology company Alios BioPharma, Inc. Prior to Alios, Dr. Brosgart served as Senior Vice President and Chief Medical Officer of Children's Hospital & Research Center in Oakland, California, from 2009 until February 2011. Previously, she served for eleven years, from 1998 until 2009, at the biopharmaceutical company Gilead Sciences, Inc., where she held a number of senior management roles, most recently as Vice President, Public Health and Policy and earlier as Vice President, Clinical Research and Vice President, Medical Affairs. Prior to Gilead, Dr. Brosgart was the Medical Director of the East Bay AIDS Center in Berkeley, California (1987-1998) and the Medical Director of the Central Health Center for the Alameda County Public Health Department (1978-1987). Dr. Brosgart received a B.S. in Community Medicine from the University of California, Berkeley and received an M.D. from the University of California, San Francisco. Her residency training was in pediatrics, public health and preventive medicine at UCSF and UC Berkeley School of Public Health. She has published extensively in the areas of HIV, HBV, CMV, and liver disease.

Marshall Heinberg joined our Board on October 14, 2018. Mr. Heinberg has extensive experience relevant to us and insight into the global capital markets and has worked with several life science and technology companies. Mr. Heinberg serves as a Senior Advisor to Burford Capital and is the founder and Managing Director of MAH Associates, LLC, which provides strategic advisory and consulting services to various companies, including the Company since 2013. Since April 2017, Mr. Heinberg has served on the board of directors of Ecology and Environment (NasdaqGM: EEI) and is currently Executive Chairman of the Board of Directors. Since January 2010, Mr. Heinberg has served on the board of directors of Universal Biosensors (UBI.AX). Mr. Heinberg began his investment banking career in 1987 in the Corporate Finance Division of Oppenheimer & Co, Inc., which was acquired by Canadian Imperial Bank of Commerce (CIBC) in 1997. Mr. Heinberg served as Head of the Investment Banking Department and as a Senior Managing Director of Oppenheimer & Co. Inc. from 2008 until 2012, and as the U.S. Head of Investment Banking at CIBC World Markets from 2001 until 2008. Mr. Heinberg has also served as a director of National Financial Partners Corp., a business that provided advisory and brokerage services to corporate and high net worth individual clients in the United States and Canada until the company was acquired by Madison Dearborn in July 2013. Mr. Heinberg was also a non-executive director of Image Entertainment, Inc., a leading independent licensee and distributor of entertainment programming in North America, until the Company was acquired in October 2012. Prior to joining Oppenheimer, Mr. Heinberg practiced corporate law for approximately four years. Mr. Heinberg has a B.S. in economics from the Wharton School at the University of Pennsylvania and a J.D. from Fordham Law School.

There are no family relationships between any director or executive officer. There are no arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any director or executive officer was selected as a director or member of senior management, as the case may be.

Scientific Advisory Board

We seek advice from our Scientific Advisory Board generally on scientific and medical matters. Our Scientific Advisory Board includes: Professor Vlad Ratziu, from the University Pierre et Marie Curie in Paris, France and coordinator of the EU FP7 FLIP consortium; Professor Scott Friedman from the Icahn School of Medicine at Mount Sinai in New York, United States; Professor Arun Sanyal, from the Virginia Commonwealth University in Richmond, Virginia; Professor Rohit Loomba, from the University of California San Diego School of Medicine in San Diego, California; Professor Jose Mato, from CIC bioGUNE and CIC biomaGUNE, Spain; and Professor Stephen Harrison, Medical Director of Pinnacle Clinical Research.

B. Compensation.

Certain Approvals Required for Office Holders' Compensation of the Companies Law

Pursuant to the Companies Law, the Company is required to adopt a compensation policy regarding the terms of office and employment of its Office Holders (as such terms are defined below), which includes exemption and release of the Office Holders from liability for breach of his or her duty of care to the Company, an undertaking to indemnify the Office Holder, post factum indemnification or insurance; any grant, payment, remuneration, compensation, or other benefit provided in connection with termination of service; and any benefit, other payment or undertaking to provide any payment as aforesaid, or the Terms of Office and Employment. The Company's current compensation policy with respect to the Terms of Office and Employment of the Company's Office Holders, or the Compensation Policy, was approved by the Board in April 2017 after considering the recommendations of the remuneration committee and was adopted by the Company's shareholders in June 2017.

The term 'Office Holder' as defined in the Companies Law includes a general manager, chief business manager, deputy general manager, vice general manager, any other person fulfilling or assuming the responsibilities of any of the foregoing positions without regard to such person's title, as well as a director, or a manager directly subordinate to the general manager or the chief executive officer. As of February 28, 2019, the latest practicable date for inclusion in this annual report, in addition to the eight members of the Board (including the Company's President and Chief Executive Officer), the Company considers four other individuals, including the Chief Medical Officer, Chief Scientist Officer, Chief Financial Officer, and Chief Operating Officer to be Office Holders.

Pursuant to the Companies Law, arrangements between the Company and its Office Holders must generally be approved by the remuneration committee and the Board and be consistent with the Compensation Policy. However, under certain circumstances, the Company may approve an arrangement that is not consistent with the Compensation Policy, if such arrangement is approved by a majority of the Company's shareholders, provided that (i) such majority includes a majority of the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded), or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the arrangement constitute two percent or less of the voting power of the company, or the Special Majority.

The terms of office and employment of directors (including an officer who is a director but is not a controlling shareholder) further require the approval of the shareholders by a simple majority in addition to the approval of the Compensation Committee and the Board, in that order, and under certain circumstances, a Special Majority; with respect to a chief executive officer or an officer who is a controlling shareholder, the approval of the shareholders must be made by the Special Majority. In addition, under certain circumstances, a company may be exempt from receiving the shareholders' approval with respect to the Terms of Office and Employment of a non-affiliated candidate for chief executive officer.

Under certain circumstances, if the terms of office and employment of Office Holders (who are not directors or controlling shareholders) are not approved by the shareholders, where such approval is required, the remuneration committee and the Board may subsequently override the resolution of the shareholders following a new discussion of the matter and for specified reasons. In addition, amendment of terms of office and employment of Office Holders (who are not directors or controlling shareholders) requires the approval of the remuneration committee only, if the remuneration committee determines that the amendment is not material.

Aggregate Executive Compensation

The aggregate compensation, including share-based compensation, paid by us to all of our Office Holders as a group, with respect to the year ended December 31, 2018, was approximately $ 3.7 million. This amount includes approximately $0.3 million set aside or accrued to provide pension, severance, retirement, vacation or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to Office Holders, and other benefits commonly reimbursed or paid by companies in our industry. In addition to the eight members of the Board (including the Company's President and Chief Executive), the Company considers six other individuals, namely the former Chairman of the Board, Chief Medical Officer, Chief Scientist Officer, Chief Financial Officer, Chief Operating Officer and the former VP, Legal and Strategy, to have been Office Holders in 2018.

As of December 31, 2018, options to purchase 1,920,046 of our ordinary shares granted to our Office Holders as a group were outstanding, of which options to purchase 1,039,994 of our ordinary shares were vested, with a weighted average exercise price of $3.28 per ordinary share.

As of December 31, 2018, 16.994 restricted stock units (RSUs) granted to our Office Holders as a group were outstanding. For outstanding equity-based awards granted to our Office Holders, see below under “Item 6. Directors, Senior Management and Employees—E. Share Ownership—Certain Information Concerning Equity Awards to Office Holders.”

Individual Compensation of Covered Executives

The following table sets forth the compensation granted to the five most highly compensated Office Holders during or with respect to the year ended December 31, 2018. All amounts reported in the table reflect the cost to the Company, as recognized in its financial statements for the year ended December 31, 2018. The five individuals for whom disclosure is provided are referred to herein as “Covered Executives.”

Information Regarding the Covered Executives	**Compensation for Services[1]**					
Name and Principal Position[1]	Base Salary/consulting fee($)	**Benefits and Perquisites ($)[2]**	**Cash Bonus ($)[3]**	**Equity-Based Compensation ($)[4]**	**Other ($)[5]**	Total ($)
Allen Baharaff (President and Chief Executive Officer and	383,653	107,116	490,928[6]	512,758	40,000	1,534,455

Director)						
Dr. Tali Gorfine (Chief Medical Officer)	140,117	35,872	46,958	97,742	-	320,688
Dr. Liat Hayardeny (Chief Scientific Officer)	136,781	36,065	46,958	96,418	-	316,222
Yohai Stenzler (Chief Financial Officer)	84,070	31,537	28,175	133,583		277,365
Guy Nehemya (Chief Operating Officer)	84,070	28,558	28,175	121,367		262,170

(1) The above-mentioned executives are all full-time employee of the Company. Mr. Baharaff also serves as a member of our Board. Cash compensation amounts denominated in currencies other than the Dollar were converted into Dollars at an exchange rate of NIS 3.60 = $1.00, which reflects the average conversion rate for fiscal year ended December 31, 2018.

(2) Amounts reported in this column include benefits and perquisites, including those mandated by applicable law. Such benefits and perquisites may include, to the extent applicable to the Covered Executives, payments, contributions and/or allocations for savings funds, pension, severance, vacation, car allowance, medical insurances and benefits, risk insurance (e.g., life, disability, accident), telephone, convalescence pay, relocation, payments for social security and other benefits and perquisites consistent with the Company’s policies.

(3) Amounts reported in this column refer to the cash bonuses provided by the Company with respect to 2018, which have been provided for in the Company's financial statements for the year ended December 31, 2018 (including if such bonuses were paid in 2019). They exclude bonuses paid in 2018 which were provided for in the Company's financial statements for previous years. Cash bonuses are paid in accordance with the Company's 2018 Annual Cash Bonus Plan and are intended to promote the Company's work plan and business strategy by rewarding officers for achievement of the Company's business and financial goals through teamwork and collaboration. Key performance indicators which are factored into cash bonus determinations are individual specific and may include: (i) major progress in research and development stages, (ii) the execution of in/out-license transactions, (iii) the execution of strategic collaboration agreements, (iv) obtaining marketing approval of a new product, and (v) raising funds throughout public offering or a private placement.

(4) Amounts reported in this column represent the expense recorded in the Company's financial statements for the year ended December 31, 2018 with respect to equity-based compensation. Assumptions and key variables used in the calculation of such amounts are discussed in Note 9 to the Financial Statements. For outstanding equity-based awards granted to Covered Executives see below under "Item 6. Directors, Senior Management and Employees—E. Share Ownership—Certain Information Concerning Equity Awards to Office Holders."

(5) Amounts reported in this column include payments made with respect to the year 2018 and recorded in the financial statements for the year ended December 31, 2018 relating to directors' fees.

(6) This cash bonus consists of: (i) an annual bonus; and (ii) a special cash bonus for meeting certain goals.

Compensation of Directors

As approved by our shareholders at our 2017 annual meeting of shareholders, in connection with their services as directors of the Company, each of our directors from time to time, including external directors, is entitled to an annual payment of $40,000, plus value-added tax, or VAT, if applicable, and with respect to an expert external director, $50,000 plus VAT, payable quarterly at the end of each quarter. Our Board has determined that each of Mr. Nir, Ms. Yaron-Eldar and Dr. Sidransky are entitled to receive compensation as an 'expert external director'. The compensation of external directors is also subject to the provisions of the Israeli regulations promulgated pursuant to the Companies Law governing the terms of compensation payable to external directors, or the Compensation Regulations, which provide that such compensation will not be less than the Minimum Amount (as such term is defined in the Compensation Regulations). See also "Item 6. Directors, Senior Management and Employees—C. Board Practices—External Directors" and "Item 7. Major Shareholders and Related Party Transactions—C. Related Party Transactions" below.

For the outstanding equity-based awards granted to our directors, see below under "Item 6. Directors, Senior Management and Employees—E. Share Ownership—Certain Information Concerning Equity Awards to Office Holders."

Employment Agreements and Arrangements with Directors and Related Parties

We entered into written employment agreements with each of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition and assignment of inventions provisions may be limited under applicable law. See “Item 3. Key Information—Risk Factors—Risks Related to Our Business, Industry and Regulatory Requirements.”

Employment Agreement with Our President and Chief Executive Officer

On December 30, 2013, we entered into a personal employment agreement with our controlling shareholder, Mr. Allen Baharaff who serves as our president, chief executive officer and as a member of our Board, as amended on March 15, 2016 and July 20, 2017, which provides that Mr. Baharaff’s terms of office and employment are for an undefined term, subject to re-approval under the Companies Law and termination in accordance with the terms of the employment agreement.

Under the terms of his employment agreement, Mr. Baharaff is entitled to a gross monthly salary of NIS 115,000. In addition, Mr. Baharaff will be entitled to the following cash bonuses based on achievement of qualitative and quantitative performance goals and objectives: (i) an annual cash bonus in an amount of up to nine times his monthly base salary, to be determined based on the achievement of certain qualitative and quantitative performance goals and objectives set by our Board and approved by our shareholders; (ii) upon execution of a Strategic Agreement (as defined below), Mr. Baharaff will be entitled to receive, subject to the discretion of the Board, a cash bonus in an amount of up to twelve times his monthly base salary. A "Strategic Agreement" means: a license agreement or any other strategic agreement (i.e. research and development, manufacture, distribution, etc.) for the U.S., Europe, Japan or China; (iii) upon consummation of a fund raising (excluding funds received from a Strategic Agreement), Mr. Baharaff will be entitled to receive, subject to the discretion of the Board, a cash bonus in an amount of up to ten times his monthly base salary if the funds received by the Company are between $8 Million to $10 million and up to twelve times his monthly base salary if the funds received by the Company are $10 million or more; (iv) upon a Change of Control Event (as defined below), Mr. Baharaff will be entitled to receive, subject to the discretion of the Board, a cash bonus in an amount of up to twelve times his monthly base salary. A "Change of Control Event" means: (a) the acquisition of the Company by another entity or individual or group of individuals by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger, share purchase or consolidation), unless the Company's shareholders of record as constituted immediately prior to any such transaction will, immediately after such transaction (by virtue of securities issued as consideration for the Company's share capital, assets or otherwise) hold more than 50% of the voting power of the surviving or acquiring entity; or (b) a sale of all or substantially all of the assets of the Company.

Mr. Baharaff will also be entitled to the following equity based compensation: (i) in the event that our options are cashed-out upon a Change of Control Event, all unvested options granted to Mr. Baharaff will vest immediately prior to the consummation of the Change of Control Event; (ii) if upon a Change of Control Event (a) Mr. Baharaff's employment as chief executive officer of the Company or the surviving entity is terminated within twelve months as of the Change of Control Event, and (b) unvested options are replaced for new options of the surviving entity as part of the Change of Control Event with a vesting schedule and terms identical to the replaced options, or the Replacement Options, then (x) all unvested Replacement Options granted to Mr. Baharaff will vest immediately prior to the termination of Mr. Baharaff's employment, and (y) Mr. Baharaff's Replacement Options will be exercisable until the earlier of (a) two years from termination, and (b) expiration of the Replacement Options.

Mr. Baharaff will also receive other benefits required under Israeli law or that are customary for senior executives in Israel such as confidentiality, reimbursement of expenses, payment for absence days, sick leave, pension and/or a manager's insurance policy and study fund.

Mr. Baharaff's employment agreement is terminable by either party upon six months prior written notice, or Prior Notice Period, and contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. Upon termination, provided such termination was not for cause, Mr. Baharaff shall be entitled, in addition to the Prior Notice Period, to a payment in an amount of up to twelve times his monthly base salary, to be paid in twelve equal monthly installments, in exchange for Mr. Baharaff's undertaking not to compete with the Company for a period of twelve months, or Non-Compete Grant. Other than in case of resignation by Mr.

Baharaff, excluding resignation for a Good Reason Event (as defined below), or termination for cause: (i) all Mr. Baharaff's unvested options will vest upon termination; and (ii) unexercised options granted to Mr. Baharaff may be exercised until the earlier of (a) two years from his termination, and (b) expiration of his options. A "Good Reason Event" means: any of the following events, provided that the event is effected by the Company without the written consent of Mr. Baharaff: (i) a material reduction or adverse change in Mr. Baharaff's authority, duties or responsibilities; (ii) a reduction in Mr. Baharaff's monthly base salary, other than a reduction of no more than 10% of his then current monthly base salary as part of an across the board reduction in all salaries for employees of the Company; (iii) a material breach by the Company of Mr. Baharaff's employment agreement or any other agreements pertaining directly to Mr. Baharaff's compensation or employment or (iv) death, disability or severe illness. Upon termination for cause by the Company, Mr. Baharaff shall not be entitled to any Prior Notice Period, Non-Compete Grant or any other payment, and any unvested outstanding equity awards shall terminate immediately upon the date of such termination for cause.

On December 13, 2018, our Board resolved to increase Mr. Baharaff's gross monthly salary to 144,375 NIS per month, commencing January 1, 2019 with such increased salary to be in effect for a period of two years. Implementation of the increase is subject to shareholder approval and is still pending.

For cash bonuses granted to Mr. Baharaff see "Item 6. Directors, Senior Management and Employees— B. Compensation—Individual Compensation of Covered Executives." For outstanding equity-based awards granted to Mr. Baharaff see below under "Item 6. Directors, Senior Management and Employees—E. Share Ownership—Certain Information Concerning Equity Awards to Office Holders."

C. Board Practices.

We are incorporated in Israel, and, therefore, we are subject to various corporate governance practices under Israeli law relating to such matters as external directors, independent directors, audit committees, remuneration committees and internal auditors. These Israeli law requirements are in addition to the requirements of the Nasdaq Listing Rules and other relevant provisions of U.S. securities laws. Under such Nasdaq Listing Rules, a foreign private issuer may generally follow its home country practices for corporate governance in lieu of such comparable listing rules' requirements, except for certain matters such as composition and responsibilities of the audit committee and the SEC-mandated standards for the independence of its members. See below under "Item 16G. Corporate Governance" for further information.

Membership of the Board

Our Articles provide that the minimum number of members of the Board is three and the maximum number of members is eleven. The Board is presently comprised of eight members, two of whom are external directors. The minimum and maximum number of directors may be changed, at any time and from time to time, by a majority vote of our directors then in office, provided that no decrease in the number of directors shall shorten the term of any incumbent director. Under our Articles, the Board consists of three classes of directors (not including the two external directors, each of whom are not part of any class) which are appointed for fixed terms of office in accordance with the Companies Law and our Articles, with one class being elected each year for a term of approximately three years by our shareholders at our annual general meeting.

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

The three classes of directors are Class I Directors, Class II Directors and Class III Directors. Allen Baharaff, Marshall Heinberg and Prof. Ran Oren serve as our Class II Directors until the close of the annual general meeting to be held in 2019; William Marth serves as our Class III Director until the close of the annual general meeting to be held in 2020; and Shmuel Nir and Dr. Carol Brosgart serve as our Class I Directors until the close of the annual general meeting to be held in 2021. In addition, our shareholders meeting held on June 7, 2017, resolved to re-elect Ms. Tali Yaron-Eldar and Dr. David Sidransky as the Company's external directors for a term of three years, commencing as of June 12, 2017.

In the annual general meeting to be convened in 2019, our Board plans to nominate Mr. Baharaff and Mr. Heinberg for re-election to serve as Class II Directors until the close of the annual general meeting to be held in 2022 and nominate Prof. Oren for re-election to serve as a Class III Director until the close of the annual general meeting to be held in 2020.

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

Any amendment of our Articles regarding the election of directors, as described above, require the affirmative vote of at least 75% of the voting rights in the Company, represented personally or by proxy and voting thereon at a general meeting. See "Item 6. Directors, Senior Management and Employees—C. Board Practices—External Directors" for a

description of the procedure for the election of external directors.

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

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

Alternate Directors

Our Articles provide, as allowed by the Companies Law, that any director may, subject to the conditions set thereto, appoint a person as an alternate to act in his place, to remove the alternate and appoint another in his place and to appoint an alternate in place of an alternate whose office is vacated for any reason whatsoever. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors so long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director, he or she is required to be an external director and to have either “financial and accounting expertise” or “professional expertise,” depending on the qualifications of the external director he or she is replacing. A person who does not have the requisite “financial and accounting experience” or the “professional expertise,” depending on the qualifications of the external director he or she is replacing, may not be appointed as an alternate director for an external director. A person who is not qualified to be appointed as an independent director, pursuant to the Companies Law, may not be appointed as an alternate director of an independent director qualified as such under the Companies Law. Unless the appointing director limits the time or scope of the appointment, the appointment is effective for all purposes until the appointing director ceases to be a director or terminates the appointment.

External Directors

Under the Companies Law and the regulations promulgated pursuant thereto, Israeli companies whose shares have been offered to the public, or that are publicly traded outside of Israel, which we refer to as a public company, are required to appoint at least two natural persons as "external directors."

No person may be appointed as an external director if such person is a relative of a controlling shareholder or if such person, a relative, partner or employer of such person, or anyone to whom such person is directly or indirectly subordinate, or any entity under such person's control, has or had, on or within the two years preceding the date of such person's appointment to serve as an external director, any affiliation with the company to whose board of directors the external director is proposed to be appointed, with any controlling shareholder of the company, with a relative of such controlling shareholder, or with any entity controlled, on the date of such appointment or within the preceding two years, by the company or by a controlling shareholder of the company. If the company has no controlling shareholder or a shareholder holding 25% or more of the company's voting rights, a person may not serve as an external director if the person has any affiliation, at the time of the appointment, to the chairman of the board of directors, the chief executive officer or the most senior financial officer of the company, or to a shareholder holding 5% or more of the outstanding shares or voting rights of the company.

The term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to have "control" of the company and thus to be a controlling shareholder of the company if the shareholder holds 50% or more of the "means of control" of the company. "Means of control" is defined as (1) the right to vote at a general meeting of a company or a corresponding body of another corporation; or (2) the right to appoint directors of the corporation or its general manager.

The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- or control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an

external director following the initial public offering.

The term “relative” is defined as a spouse, sibling, parent, grandparent, descendant, spouse’s descendant, sibling and parent and the spouse of each of the foregoing.

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

Pursuant to the Companies Law, an external director is required to have either financial and accounting expertise or professional qualifications according to criteria set forth in regulations promulgated under the Companies Law, provided that at least one of the external directors has financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the Nasdaq requirements for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications as required under the Companies Law and regulations promulgated thereunder.

The regulations promulgated under the Companies Law define an external director with requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration, (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to his or her office as an external director in the company, or (3) the director has at least five years of experience serving in any one of the following capacities, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a substantial scope of business, (b) a senior position in the company's primary field of business or (c) a senior position in public administration.

The board of directors must make the determination as to the financial and accounting expertise, and as to the professional qualifications, of a director taking into consideration those criteria and matters set forth in the regulations. A director with financial and accounting expertise is a director who by virtue of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements so that he or she is able to fully understand our financial statements and initiate debate regarding the manner in which the financial information is presented. In addition, the board of directors of a public company is required to make a determination as to the minimum number of directors who must have such financial and accounting expertise based on, among other things, the type of company, its size, the volume and complexity of the company's activities and the number of directors. Our Board has determined that the minimum number of directors with financial and accounting expertise, in addition to the external director or directors who have such expertise, will be one, and that Mr. Marth qualifies as such. The external director who qualifies to have such expertise is Ms. Yaron-Eldar. In addition, our Board has determined that Ms. Yaron-Eldar qualifies as an audit committee financial expert pursuant to the applicable SEC rules, and accordingly as having the necessary financial sophistication as required by the Nasdaq Capital Market rules.

Election and Dismissal of External Directors

External directors are elected for a term of three years at the general meeting of shareholders by a simple majority, provided that the majority includes either:

- a majority of the shares that are voted at the meeting in favor of the election of the external director, excluding abstentions, include at least a majority of the votes of shareholders who are not controlling shareholders and who do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder), or

- the total number of shares held by the shareholders mentioned in the paragraph above that are voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

External directors may be re-elected for two additional terms of three years each, provided that with respect to the appointment for each such additional three year term, one of the following has occurred:

- his/her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders' meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company, subject to additional restrictions set forth in the Companies Law with respect to the affiliation of the external director nominee;

- the external director proposed his or her own nomination, and such nomination was approved in accordance with the requirements described in the paragraph above; or

- the reappointment of the external director has been proposed by the board of directors and the appointment was approved by the majority of shareholders required for the initial appointment of an external director.

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

Following termination of service as an external director, a public company, a controlling shareholder thereof and any entity controlled by a controlling shareholder, may not grant any benefit, directly or indirectly, to any person who served as an external director of such public company, or to his or her spouse or child, including, not appointing such person, or his or her spouse or child, as an Office Holder of such public company or of any entity controlled by a controlling shareholder of such public company, not employing such person or his or her spouse or child and not receiving professional services for pay from such person, either directly or indirectly, including through a corporation controlled by such person, all until the lapse of two years from termination of office with respect to the external director, his or her spouse or child; and until the lapse of one year from termination of office with respect to other relatives of the former external director.

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

Under the Companies Law, an external director cannot be dismissed from office unless the board of directors has learned there is a concern that: the external director no longer meets the statutory requirements for his appointment as an external director; or the external director is in breach of his or her duty of loyalty to the company. The board of directors shall discuss the matter no later than in the first board of directors meeting convened after the board had become aware of such circumstances. In the event the board of directors has determined that an external director had ceased to comply with the requirements set forth under the Companies Law or that he or she breached his or her duty of loyalty to the company, than the board of directors shall convene a general meeting of the shareholders and will include on the agenda a resolution for the removal from office of such external director. The shareholders vote required to removal of an external director from office is the same majority required for the appointment; provided, however, that the external director has been given the opportunity to present his or her position. In addition, a court of law may determine, upon a request of a director or a shareholder, to dismiss the external director after finding that such external director no longer meets the statutory requirements of an external director set under the Companies Law or that the external director is in breach of his or her duty of loyalty to the company.

In addition, under regulations promulgated pursuant to the Companies Law, companies with no controlling shareholder whose shares are listed for trading on specified exchanges outside of Israel, including the Nasdaq Capital Market, may adopt exemptions from various corporate governance requirements of the Companies Law so long as the company satisfies the applicable foreign country laws and regulations, including applicable stock exchange rules, that apply to companies organized in that country relating to the appointment of independent directors and the composition of audit and compensation committees. Such exemptions include an exemption from the requirement to appoint external directors and the requirement that an external director be a member of certain committees. We may use these exemptions in the future if we do not have a controlling shareholder.

Ms. Yaron-Eldar and Dr. Sidransky are the current external directors, appointed by our Board and approved by our shareholders to serve as such.

Independent Directors Under the Companies Law

Under the Companies Law an "independent director" is either an external director or a director appointed or classified as such who meets the same non-affiliation criteria as an external director, as determined by the audit committee, and who has not served as a director of the company for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service.

Regulations promulgated pursuant to the Companies Law provide that a director in a public company whose shares are listed for trading on specified exchanges outside of Israel, including the Nasdaq Capital Market, such as the Company, who qualifies as an independent director under the relevant non-Israeli rules relating to independence standards for audit committee membership and who meets certain non-affiliation criteria, which are less stringent than those applicable to external directors, would be deemed an "independent" director pursuant to the Companies Law provided: (i) he or she has not served as a director for more than nine consecutive years; (ii) he or she has been approved as such by the audit committee; and (iii) his or her remuneration shall be in accordance with the Compensation Regulations. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service.

Furthermore, pursuant to these regulations, such company may reappoint a person as an independent director for additional terms, beyond nine years, which do not exceed three years each, if each of the audit committee and the board of directors determine, in that order, that in light of the independent director's expertise and special contribution to the board of directors and its committees, the reappointment for an additional term is in the company's best interest.

Committees of the Board

Our Articles also provide that the Board may delegate any, or all, of its powers to one or more committees of the Board, and may entrust to and confer upon a "managing director" such of its powers as it deems appropriate. However, the Companies Law provides that certain powers and authorities (for example, the power to approve the financial statements) may not be delegated and may be exercised only by the Board. Notwithstanding the foregoing, we currently do, and intend to continue to, comply with the corporate governance requirements of the Nasdaq Capital Market, except to the extent indicated elsewhere in this annual report, including as set forth under "Item 16G. Corporate Governance" below. The Companies Law requires public companies such as the Company to appoint an audit committee and a remuneration committee.

Audit Committee

The Companies Law requires public companies to appoint an audit committee comprised of at least three directors, including all of the external directors, the majority of whom must be independent directors under the Companies Law. The Companies Law further stipulates that the following may not be members of the audit committee: (i) the chairman of the board of directors; (ii) any director employed by or providing services on an ongoing basis to the company, to a controlling shareholder of the company or an entity controlled by a controlling shareholder of the company; (iii) a director whose livelihood mainly depends on a controlling shareholder; and (iv) a controlling shareholder or any relative of a controlling shareholder.

The Companies Law further requires that: (i) the chairperson of the audit committee must be an external director; (ii) generally, any person who is not entitled to be a member of the audit committee may not attend the audit committee's meetings and voting sessions, unless such person was invited by the chairperson of the committee for the purpose of presenting a specific subject matter thereof; and (iii) the quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee is a majority of the members of the audit committee, provided that the majority of the members present are independent directors and at least one of them is an external director.

The responsibilities of the audit committee under the Companies Law include: (i) identifying flaws in the management of a company's business and making recommendations to the board of directors as to how to correct them; (ii) with respect to certain actions involving conflicts of interest and with respect to certain related party transactions, deciding whether such actions are material actions and whether such transactions are extraordinary transactions, respectively, all for the purpose of approving such actions or transactions; (iii) reviewing and deciding whether to approve certain related party transactions and certain actions involving conflicts of interest; (iv) reviewing the internal auditor's work program; (v) examining the company's internal control structure and processes, the performance of the internal auditor and whether the internal auditor has at his or her disposal the tools and resources required to perform his or her duties,

considering, inter alia, the special needs of the company and its size; (vi) examining the independent auditor's scope of work as well as the independent auditor's fees and providing its recommendations to the appropriate corporate organ; (vii) providing for arrangements as to the manner in which the company will deal with employee complaints with respect to deficiencies in the management of the company's business and the protection to be provided to such employees; and (viii) with respect to related party transactions with a controlling shareholder, regardless of whether such transactions are extraordinary transactions, that prior to entering into such transaction, to establish the requirement of having a competitive process under the supervision of the audit committee or any individual, committee or body on its behalf and according to criteria established by the audit committee and to determine procedures for approving certain related party transactions with a controlling shareholder, which were determined by the audit committee to be non-extraordinary transactions, but which are not negligible transactions.

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

Our audit committee oversees the accounting and financial reporting processes of the Company. It also provides assistance to the Board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, auditing, financial reporting and internal control functions of the Company. In carrying out its duties, our audit committee meets with management at least once a quarter, at which time, among other things, it reviews, and either approves or disapproves, the financial results of the Company for the immediately preceding calendar quarter and conveys its conclusions in this regard to the Board. Our audit committee also monitors generally the services provided by the Company's independent auditors to ensure their independence and reviews all audit and non-audit services provided by them.

Our Board has resolved to delegate to the audit committee the power to pre-approve non-auditing services rendered by the Company's independent auditors without the need for further approval by our Board. As such, on March 10, 2019, our audit committee approved the adoption of a pre-approval policy, such that the Chairman of the audit committee is authorized to pre-approve any engagement of our independent auditors during a period of twelve months from the date of such approval, for the provision of non-auditing services, for fees not to exceed $20,000, and any such engagement which exceeds $20,000 shall require a pre-approval by the entire audit committee. Once services have been pre-approved, our management must then report to the audit committee on a periodic basis regarding the extent of services actually provided in accordance with the pre-approval policy, and regarding the fees for the services performed. Such fees for 2017 were pre-approved by the audit committee in accordance with the pre-approval policy.

The Company's independent and internal auditors also report regularly to our audit committee, and our audit committee discusses with the Company's independent auditors the quality, not just the acceptability, of the accounting principles, the reasonableness of significant judgments and the clarity of disclosures in the Company's financial statements, as and when it deems it appropriate to do so.

Under the provisions of the Sarbanes-Oxley Act, the audit committee is directly responsible for the appointment, compensation and oversight of the work of the company's independent auditors. However, under Israeli law, the appointment of independent auditors and their compensation require the approval of the shareholders of a public company. Pursuant to Israeli law, the shareholders may delegate the authority to determine the compensation of the independent auditors to the board of directors. In addition, pursuant to the Companies Law, the audit committee is required to examine the independent auditors' fees and to provide its recommendations with respect thereto to the appropriate corporate body. Accordingly, the appointment of our independent auditors is required to be approved and recommended to the shareholders by our audit committee and Board and approved by the shareholders. The compensation of the independent auditors for audit services is required to be approved and recommended to the Board by our audit committee and approved by the Board. The Board has delegated its authority to approve the compensation of independent auditors for non-auditing services to the audit committee.

Mr. Nir, Ms. Yaron-Eldar and Dr. Sidransky are the current members of our audit committee, with Ms. Yaron-Eldar serving as chairperson. Each of our audit committee members are "independent directors" in accordance with the Nasdaq Capital Market corporate governance requirements, as affirmatively determined by our Board, and Ms. Yaron-Eldar and Dr. Sidransky also meet the qualifications for service as "external directors" under the Companies Law and the regulations promulgated thereunder, also as affirmatively determined by our Board and our shareholders. In addition, our Board has affirmatively determined that Ms. Yaron-Eldar also qualifies as an audit committee financial expert pursuant to the applicable SEC rules, and accordingly has the necessary financial sophistication as required by the Nasdaq Capital Market rules, and as a financial and accounting expert under the Companies Law.

Remuneration Committee

The Companies Law requires public companies to appoint a remuneration committee comprised of at least three directors, including all of the external directors, who must generally also constitute a majority of the members. All other members of the committee, who are not external directors, must be directors who receive compensation consistent with that of external directors and that is in compliance with the Compensation Regulations. In addition, the chairperson of the remuneration committee must be an external director.

The Companies Law further stipulates that directors who are not qualified to serve on the audit committee, as described above, may not serve on the remuneration committee either and that similar to the audit committee, generally, any person who is not entitled to be a member of the remuneration committee may not attend the

remuneration committee's meetings. Our Board has adopted a remuneration committee charter setting forth the responsibilities of our remuneration committee, as described below.

The responsibilities of the remuneration committee under the Companies Law include: (i) making recommendations to the board of directors with respect to the approval of the compensation policy and any extensions thereto; (ii) periodically reviewing the implementation of the compensation policy and providing the board of directors with recommendations with respect to any amendments or updates thereto; (iii) reviewing and resolving whether or not to approve transactions with respect to the terms of office and employment of Office Holders; and (iv) resolving, under certain circumstances prescribed under the Companies Law, whether or not to exempt a transaction with a candidate for chief executive officer who meets non-affiliation criteria from shareholder approval.

Our remuneration committee also oversees the administration of the Company's various compensation plans and arrangements, in particular, the incentive compensation, deferred compensation and equity based plans of the Company (and to the extent appropriate, of the subsidiaries of the Company) and assists the Board in fulfilling its responsibilities relating to the compensation of directors, the Chief Executive Officer and other Office Holders of the Company. In carrying out these duties, our remuneration committee meets on an ad hoc basis. Under the Companies Law, our remuneration committee may need to seek the approval of the Board and the shareholders for certain compensation decisions as described above. Each member of our remuneration committee is an "independent director" in accordance with the Nasdaq Capital Market corporate governance requirements, as affirmatively determined by our Board. Mr. Nir, Ms. Yaron-Eldar and Dr. Sidransky are the current members of our remuneration committee, with Ms. Yaron-Eldar serving as chairperson.

Nominating Committee

The Nasdaq Capital Market corporate governance requires each company adopting a nominating committee to certify that it has adopted a formal written charter or board resolution, as applicable, addressing the nominations process and such related matters as may be required under U.S. federal securities laws. Although not required as a foreign private issuer to adopt a nominating committee, we have decided to follow such requirement.

Our Board has adopted a nominating committee charter setting forth the responsibilities of the nominating committee consistent with the Nasdaq Listing Rules.

The nominating committee is responsible for identifying individuals qualified to be appointed as board members, and recommending to the Board of appropriate director nominees for election at the general meeting of shareholders.

Independent director oversight of nominations enhances investor confidence in the selection of well-qualified director nominees, as well as independent nominees as required by the rules. The Nasdaq Capital Market listing rule is also intended to provide flexibility for a company to choose an appropriate board structure and reduce resource burdens, while ensuring that independent directors approve all nominations.

Ms. Yaron-Eldar, Mr. Marth and Dr. Sidransky are the current members of our nominating committee, with Dr. Sidransky serving as chairperson. Nasdaq Capital Market Listing Rule 5605(e) requires that our nominating committee be comprised solely of independent directors unless the nominating committee is comprised of at least three members and the Board determines that such non-independent director’s membership, which shall not be longer than two years, is required by the best interests of the Company and our shareholders.

R&D Committee

Our R&D Committee, which was established by the Board on May 2014, advises and assists the Board in its oversight of our research and development programs, including the rationale and timeline of clinical trials and other studies, as well as market surveys in connection therewith. The R&D Committee operates in accordance with the purposes and objectives determined by the Board from time to time. Dr. Sidransky, Dr. Oren and Dr. Brosgart are the current members of our R&D Committee, with Dr. Sidransky serving as chairperson.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee and nominated by the board of directors. The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. An internal auditor should comply with the requirements of the Companies Law and the Internal Audit Law, 5752-1992, and may not be:

(a) a person (or a relative of a person) who holds more than 5% of the Company's outstanding shares or voting rights;

(b) a person (or a relative of a person) who has the power to appoint a director or the general manager of the Company;

(c) an Office Holder, including a director, of the Company (or a relative thereof); or

(d) a member of the Company's independent accounting firm, or anyone on his or her behalf.

Pursuant to Israeli law, an internal auditor's tenure cannot be terminated without his or her consent, nor can he or she be suspended from such position unless the board of directors of the company has so resolved following the recommendations of the company's audit committee and, after providing the internal auditor with the opportunity to present his or her position to the board of directors of the company and to the audit committee.

On March 12, 2019, our Board re-appointed Alon Amit, CPA, from Raveh Ravid & Co. CPA, Tel Aviv, Israel, as the Company's internal auditor, effective as of January 1, 2019, for a period of two years.

Exculpation and Indemnification of Directors and Officers

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

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Under the Companies Law, and the Securities Law, 5738—1968, or the Securities Law, a company may indemnify, or undertake in advance to indemnify, an Office Holder for the following liabilities and expenses, imposed on Office Holder or incurred by Office Holder due to acts performed by him or her as an Office Holder, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an Office Holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;

- reasonable litigation expenses, including attorneys' fees, incurred by the Office Holder as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such Office Holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent or as a monetary sanction;

- a monetary liability imposed on him or her in favor of an injured party at an Administrative Procedure (as defined below) pursuant to Section 52(54)(a)(1)(a) of the Securities Law;

- expenses incurred by an office holder or certain compensation payments made to an injured party that were instituted against an office holder in connection with an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees; and

- reasonable litigation expenses, including attorneys' fees, incurred by the Office Holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third-party, or in connection with criminal proceedings in which the Office Holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

- An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

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

- a breach of the duty of loyalty to the company, provided that the Office Holder acted in good faith and had a reasonable basis to believe that such act would not prejudice the company;

- a breach of the duty of care to the company or to a third-party;

- a monetary liability imposed on the Office Holder in favor of a third-party;

- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and

- expenses incurred by an office holder in connection with an Administrative Procedure instituted against him or her, including reasonable litigation expenses and reasonable attorneys' fees.

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

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company in the event Office Holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the Office Holder;

- an act or omission committed with intent to derive unlawful personal benefit; or

- a fine, monetary sanction, penalty or forfeit levied against the Office Holder.

Under the Companies Law, exculpation, indemnification and insurance of Office Holders require the approval of the remuneration committee, board of directors and, in certain circumstances, the shareholders, as described above under "Item 6—Directors, Senior Management and Employees—B. Compensation."

Our Articles permit us to exculpate, indemnify and insure our Office Holders to the fullest extent permitted by the Companies Law. Each of our Office Holders have entered into an indemnification agreement with us, exculpating them, to the fullest extent permitted by Israeli law, from liability to us for damages caused to us as a result of a breach of the duty of care and undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from certain acts performed by such Office Holders in their capacity as an Office Holder of the Company, our subsidiaries or our affiliates.

In the opinion of the SEC, indemnification of directors and Office Holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

Agreements with Directors

Other than a written agreement with our President and Chief Executive Officer, as detailed in "Item 6. Directors, Senior Management and Employees—B. Compensation—Employment Agreements and Arrangements with Directors and Related Parties—Employment Agreement with Our President and Chief Executive Officer," we do not have written agreements

with any director providing for benefits upon the termination of his or her services with our Company.

D. Employees.

As of December 31, 2018, we had twenty-one employees, of which seventeen were full-time employees and four were part-time employees. Fifteen of the Company's employees were involved in our clinical and product development operations and six served in general and administrative capacities.

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

E. Share Ownership.

The following table sets forth information regarding beneficial ownership of our ordinary shares as of February 28, 2019, the latest practicable date for inclusion in this annual report, held by our directors and executive officers, individually and as a group and beneficial owners of more than 5% of our outstanding shares.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to ordinary shares. Ordinary shares issuable under share options, warrants or other conversion rights currently exercisable or that are exercisable within 60 days after February 28, 2019 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options, warrants or other conversion rights, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. Percentage of shares beneficially owned is based on 21,113,066 ordinary shares outstanding on February 28, 2019.

	As of February 28, 2019 **Number of ordinary shares beneficially owned(1)**	Percentage of ordinary shares beneficially owned	
More than 5% Holders			
BVF Inc.(2)	1,878,508	8.9	%
683 Capital Management, LLC(3)	1,350,000	6.4	%
Directors and Executive Officers			
Allen Baharaff(4)	4,075,467	18.7	%
Shmuel Nir(5)	87,990	*	
William Marth(6)	69,939	*	
Tali Yaron-Eldar(7)	37,969	*	
Dr. David Sidransky(8)	37,969	*	
Prof. Ran Oren(9)	102,277	*	
Dr. Carol L. Brosgart(10)	20,000	*	
Marshall Heinberg(11)	28,029	*	
Dr. Tali Gorfine(12)	27,500	*	
Dr. Liat Hayardeny(13)	25,000	*	
Yohai Stenzler(14)	36,352	*	
Guy Nehemya(15)	33,852	*	
All directors and executive officers as a group (12 persons)	**4,582, 342**	21.1	%

*Less than 1%.

(1) All options or warrants included are either currently exercisable or will be exercisable within 60 days of February 28, 2019.

(2) Based upon information contained in a Statement on Schedule 13G filed by the shareholder on February 14, 2019. Shares beneficially owned consist of (i) 923,424 ordinary shares held directly by Biotechnology Value Fund, L.P., or BVF, (ii) 710,895 ordinary shares held directly by Biotechnology Value Fund II, L.P., or BVF2, and (iii) 135,355 ordinary shares held directly by Biotechnology Value Trading Fund OS LP, or Trading Fund OS. BVF Partners OS Ltd. (“Partners OS”), as the general partner of Trading Fund OS, may be deemed to have beneficial ownership of the ordinary shares beneficially owned by Trading Fund OS. BVF Partners L.P., or Partners, as the general partner of BVF, and BVF2, as the investment manager of Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own 1,878,508 ordinary shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, and certain Partners managed accounts, or the Partners Managed Accounts, including 108,384 ordinary shares held in the Partners Managed Accounts. BVF Inc., as the general partner of Partners, may be deemed to beneficially own 1,878,508 ordinary shares beneficially owned by Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 1,878,508 ordinary shares beneficially owned by BVF Inc. The foregoing excludes 1,000,000 warrants exercisable for an aggregate of

1,000,000 ordinary shares beneficially owned by the foregoing persons, which are subject to a 4.99% beneficial ownership limitation. Partners OS disclaims beneficial ownership of the ordinary shares beneficially owned by Trading Fund OS. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the ordinary shares beneficially owned by BVF, BVF2, Trading Fund OS, and the Partners Managed Accounts.

(3) Based upon information contained in a Statement on Schedule 13G/A filed by the shareholder on June 22, 2018. 683 Capital Management, LLC, as the Investment Advisor of 683 Capital Partners, LP, may be deemed to have beneficially ownership of the 1,350,000 ordinary shares beneficially owned by 683 Capital Partners, LP. Ari Zweiman, as the Managing Member of 683 Capital Management, LLC, may be deemed to have beneficially ownership of the 1,350,000 ordinary shares beneficially owned by 683 Capital Management, LLC.

(4) Consists of (i) 3,420,822 ordinary shares, of which 3,416,822 are held through G. Yarom Medical Research Ltd., a company incorporated under the laws of the State of Israel, of which Mr. Baharaff is the controlling shareholder and the chairman of its board of directors and 4,000 ordinary shares held by Mr. Baharaff, which were purchased in the open market; and (ii) options to purchase 654,645 ordinary shares that are currently exercisable within 60 days as of February 28, 2019. Of the 4,075,467 ordinary shares, Mr. Baharaff exercises sole voting and dispositive power over 658,645 shares beneficially owned and shared voting and dispositive power with G. Yarom Medical Research Ltd. over 3,416,822 shares.

(5) Consists of (i) 47,532 ordinary shares, of which 41,438 ordinary shares are held through Tushia Consulting Engineers Ltd., of which Shmuel Nir is its controlling shareholder and 6,094 ordinary shares held by Mr. Nir; and (ii) 40,458 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(6) Consists of (i) 20,898 ordinary shares held by Mr. Marth; and (ii) 49,041 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(7) Consists of (i) 6,094 ordinary shares held by Ms Yaron-Eldar; and (ii) 31,875 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(8) Consists of (i) 6,094 ordinary shares held by Dr. Sidransky; and (ii) 31,875 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(9) Consists of 102,277 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(10) Consists of 20,000 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(11) Consists of 28,029 ordinary shares held by Mr. Heinberg.

(12) Consists of 27,500 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(13) Consists of 25,000 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2019.

(14) Consists of (i) 4,218 ordinary shares held by Mr. Stenzler; (ii) 31,781 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2018; and (iii) 352 ordinary shares issuable upon the vesting of restricted stock units that are currently vested or will vest within 60 days as of February 28, 2019.

(15) Consists of (i) 4,218 ordinary shares held by Mr. Nehemya; (ii) 29,281 ordinary shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days as of February 28, 2018; and (iii) 352 ordinary shares issuable upon the vesting of restricted stock units that are currently vested or will vest within 60 days as of February 28, 2019.

This table is based upon information supplied by officers and directors and is believed to be accurate. Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders.

To our knowledge, as of February 28, 2019, we had two holders of record of our ordinary shares with a U.S. address, including Cede & Co., the nominee of The Depository Trust Company. These holders held in the aggregate 16,640,467 ordinary shares, or 78.8% of our outstanding ordinary shares as of February 28, 2019. The number of record holders in the United States is not representative of the number of beneficial holders of our ordinary shares nor is it representative of where such beneficial holders are resident since many of these ordinary shares were held by brokers or other nominees.

To our knowledge, the only significant changes in the percentage ownership held by our major shareholders during the past approximate three years have been the following: from January 1, 2016 to February 28, 2019, (i) the ownership percentage of Chaim Hurvitz decreased by 2.6% from 7.3% to 4.7%, (ii) the ownership percentage of Allen Baharaff decreased by 9.0% from 27.8% to 18.8%, and (iii) during 2018, BVF, Inc. and 683 Capital Management, LLC became beneficial owners of more than 5% of our outstanding shares.

2013 Incentive Share Option Plan

We maintain one equity-based incentive plan, our 2013 Incentive Share Option Plan, or the 2013 Plan. As of February 28, 2019, the latest practicable date for inclusion in this annual report, a total of 4 shares were reserved for issuance under our 2013 Plan, of which (1) options to purchase 2,349,054 ordinary shares and 13,869 restricted stock units, or RSUs, were issued and outstanding thereunder (i.e., were granted but not canceled, expired or exercised); (2) options to purchase 1,147,988 ordinary shares were exercised and 41,462 ordinary shares were issued upon vesting of RSUs, and (3) 784,047 shares remain unallocated for future equity awards pursuant to our 2013 Plan.

Our 2013 Plan, which was adopted by our Board on September 2, 2013, and approved by our shareholders in December 30, 2013 (as was amended by the Board and our shareholders on March 30, 2015, May 11, 2015, and August 30, 2018), provides for the grant of options to purchase our ordinary shares and the issuance of RSUs to our officers, directors, employees, service providers and consultants. Our 2013 Plan provides for such equity-based compensation under various and different tax regimes, including those detailed below.

The 2013 Plan is administered by our Board, which, on its own or upon the recommendation of our remuneration committee or any other similar committee of the Board, shall determine, subject to applicable law, the identity of grantees of awards and various terms of the grant. Consistent with our Compensation Policy, the 2013 Plan provides for granting options to purchase our ordinary shares pursuant to Section 102 of the Israeli Income Tax Ordinance, or the Ordinance, under the capital gains route, to directors, officers and employees who are Israeli residents holding (or have a right to hold or to purchase) less than 10% of our total share capital and do not have a right to receive 10% or more of the Company's profits.

Section 102 of the Ordinance allows Israeli employees, directors and officers, who are not controlling shareholders to receive favorable tax treatment for compensation in the form of shares or options. However, under this route we are not allowed to deduct any expense with respect to the issuance of the options or shares. Israeli non-employee service providers, consultants and shareholders who hold 10% or more of our total share capital or are otherwise controlling shareholders, may be granted options pursuant to Section 3(i) of the Ordinance, which does not provide for similar tax benefits. In order to comply with the terms of the capital gains route pursuant to Section 102 of the Ordinance, the granted options as well as the ordinary shares issued upon exercise of these options and other shares received subsequently following any realization of rights with respect to such options (such as share dividends and share splits), must be granted to a trustee for the benefit of the relevant grantee and should be held by the trustee for at least two years after the date of the grant. If such options or shares are sold by the trustee or are transferred to the grantee before the end of the two-year period, then the grantee would be taxed at top marginal rates upon selling the shares.

For residents, or deemed residents, of the United States, the 2013 Plan provides grants, which are pursuant to Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, as incentive stock options, or ISOs, and any

other participants which do not qualify for ISOs, as non-statutory stock options, or NSOs, pursuant to the Code.

Section 422 of the Code allows employees, directors and officers, who are non-controlling shareholders (e.g., less than 10% shareholders) and are considered residents of the United States or those who are deemed to be residents of the United States for purposes of the payment of tax, or are otherwise subject to taxation in the United States with respect to the grant of awards, to receive favorable tax treatment for compensation in the form of shares or ISOs. 10% shareholders or persons which are not service providers will receive NSOs, which do not entitle them to receive similar tax benefits. Section 422(b) of the Code provides for the ISO track such that the individual does not have to pay ordinary income tax (nor employment taxes) on the difference between the exercise price and the fair market value of the shares issued (however, the holder may have to pay U.S. alternative minimum tax instead). However, if the shares are held for one year from the date of exercise and two years from the date of grant, then the profit (if any) made on sale of the shares is taxed as long-term capital gain. Section 422 of the Code requires that any grant of awards shall not be made at a price which is less than 100% of the fair market value of such awards on the date of the grant, all pursuant to the terms of Section 409A of the Code. However, under this ISO track, we are not allowed to deduct any expense with respect to the issuance of the options or shares. In order to comply with the terms of the ISO track, the option granted thereunder must meet the requirements of Section 422 of the Code when granted and at all times until the exercise thereof.

Options and RSUs granted under the 2013 Plan will vest in accordance with the vesting dates as determined by the Board following the recommendation of the remuneration committee or any other similar committee of the Board with respect to each grant. Generally, options that are not exercised within ten years from the grant date expire, unless otherwise determined by the Board and the remuneration committee, as applicable, provided, however, that, pursuant to our Compensation Policy, any equity-based awards to Office Holders must include both a gradual vesting period of at least three years from the date of grant, and an exercise period of no more than ten years from the date of grant.

Upon such date or dates designated in the applicable award agreement, unless earlier forfeited, subject to the receipt of any approvals required from any relevant tax authority, we shall settle each RSU upon vesting by delivering one ordinary share.

In case of termination for reasons of disability or death, the grantee or his legal successor may exercise options that have vested prior to termination within a period of twelve months from the date of disability or death. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested unexercised options will expire and terminate on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may exercise his or her vested options within 90 days of the date of termination or within a longer period under specified circumstances determined by our Board. Any expired or unvested options shall return to the option pool reserved under the 2013 Plan for reissuance.

In the event of grantee's termination prior to a vesting date by reason of such grantee's death or disability, all of such grantee's RSUs shall immediately become vested as of the date of such termination. In the event of a grantee's termination for cause prior to settlement, all of such grantee's RSUs shall immediately be forfeited for no consideration as of the date of such termination. If a grantee's employment or service is terminated for any other reason, (1) all vesting with respect to such grantee's RSUs shall cease, (2) all of such grantee's unvested RSUs shall immediately be forfeited for no consideration as of the date of such termination, and (3) to the extent not already settled, all of such grantee's vested RSUs shall be settled in accordance with the settlement schedule set forth in the applicable award agreement.

In the event of a merger or consolidation of our company subsequent to which we would no longer exist as a legal entity, or a sale of all, or substantially all, of our ordinary shares or assets or other transaction having a similar effect on us, or a Transaction, any unexercised options then outstanding will be cancelled. Notwithstanding the foregoing, the Board, or the relevant committee of the Board, may determine that the options will not be cancelled but will be assumed or substituted for an appropriate number of the same type of shares or other securities of the successor company as were distributed to the Company or the shareholders in connection with the Transaction. In addition, the Board, or the relevant committee of the Board, may determine to include in certain option agreements either a clause that provides for acceleration of vesting of all or part of the unvested options in the event of a Transaction or the occurrence of another event or a clause which provides that if the optionee's employment with the successor company is terminated by the successor company without cause within a certain period, not to exceed two years from the closing of such Transaction, all or part of the unvested options shall be accelerated.

Certain Information Concerning Equity Awards to Office Holders

The following tables set forth information, as of February 28, 2019 concerning all outstanding equity awards to Office Holders as of such date.

Options

Name of Office Holder	Date of grant	Exercise price per share ($)	Shares subject to the option		Shares vested and unexercised	Shares unvested	Schedule date of expiration
Allen Baharaff	December 30, 2013	NIS0.01	90,886		90,886	0	Sep-2-2023
	December 30, 2013	NIS0.01	266,085		266,085	0	Sep-2-2023
	December 30, 2013	NIS0.01	30,174		30,174	0	Sep-2-2023
	February 4, 2016	$5.49	140,000	(1)	140,000	46,667	Feb-04-2026
	February 4, 2016	$5.94	170,000		127,500	42,500	Feb-04-2026
	July 10, 2018	$11.56	220,000		0	220,000	Jul-10-2028
William Marth	March 18, 2014	$3.57	17,166		17,166	0	Sep-02-2023
	May 11, 2015	$5.49	10,000		9,375	625	May-11-2025
	February 4, 2016	$5.94	30,000		22,500	7,500	Feb-04-2026
	July 10, 2018	$11.56	30,000		0	30,000	Jul-10-2028
Shmuel Nir	February 21, 2014	$3.57	8,583		8,583	0	Sep-02-2023
	May 11, 2015	$5.49	10,000		9,375	625	May-11-2025
	February 4, 2016	$5.94	30,000		22,500	7,500	Feb-04-2026
	July 10, 2018	$11.56	30,000		0	30,000	Jul-10-2028
Tali Yaron-Eldar	May 11, 2015	$5.49	10,000		9,375	625	May-11-2025
	February 4, 2016	$5.94	30,000		22,500	7,500	Feb-04-2026
	July 10, 2018	$11.56	30,000		0	30,000	Jul-10-2028

David Sidransky	May 11, 2015	$5.49	10,000	9,375	625	May-11-2025
	February 4, 2016	$5.94	30,000	22,500	7,500	Feb-04-2026
	July 10, 2018	$11.56	30,000	0	30,000	Jul-10-2028
Prof. Ran Oren	December 22, 2013	$3.57	64,125	64,125	0	Sep-02-2023
	January 3, 2016	$7.61	30,000	22,500	7,500	Jan-03-2026
	July 28, 2016	$4.47	20,000	12,500	7,500	July-28-2026
	July 10, 2018	$11.56	30,000	0	30,000	Jul-10-2028
Dr. Tali Gorfine	July 28, 2016	$4.47	25,000	10,000	15,000	July-28-2026
	January 31, 2017	$3.84	35,000	15,000	20,000	Jan-31-2026
	July 10, 2018	$11.56	40,000	0	40,000	Jul-10-2028
Dr. Liat Hayardeny	September 6, 2016	$4.05	32,500	15,000	17,500	Sep-06-2026
	January 31, 2017	$3.84	27,500	7,500	20,000	Jan-31-2026
	July 10, 2018	$11.56	40,000	0	40,000	Jul-10-2028
Yohai Stenzler	December 30, 2014	$5.49	3,500	3,500	0	Dec-30-2024
	January 3, 2016	$7.61	22,500	16,875	16,875	Jan-03-2026
	November 7, 2017	$7.48	20,000	8,333	11,667	Nov-07-2020
	July 10, 2018	$11.56	40,000	0	40,000	Jul-10-2028
Guy Nehemya	December 30, 2014	$5.49	11,000	11,000	0	Dec-30-2024
	January 3, 2016	$7.61	22,500	16,875	16,875	Jan-03-2026
	July 10, 2018	$11.56	40,000	0	40,000	Jul-10-2028
Carol L. Brosgart	April 25, 2017	$4.87	20,000	20,000	0	Apr-25-2027
	July 10, 2018	$11.56	30,000	0	30,000	Jul-10-2028

On November 1, 2018, our remuneration committee and Board approved the grant to Marshall Heinberg of options to purchase 30,000 ordinary shares under our 2013 Plan, subject to shareholder approval which is still pending. The options shall have an exercise price of $8.95 per share, shall vest over a period of four years, with one quarter vesting on the first anniversary of the date of grant and the remainder vesting on an equal quarterly basis and have a term of ten years.

RSUs

Name of Office Holder	Date of grant	Shares subject to the RSUs	Shares vested	Shares unvested
William Marth	Feb-04-2016	7,500	5,625	1,875
Shmuel Nir	Feb-04-2016	7,500	5,625	1,875

Tali Yaron-Eldar	Feb-04-2016	7,500	5,625	1,875
David Sidransky	Feb-04-2016	7,500	5,625	1,875
Yohai Stenzler	Jan-03-2016	5,625	4,218	1,407
Guy Nehemya	Jan-03-2016	5,625	4,218	1,407

ITEM 7. Major Shareholders and Related Party Transactions.

A. Major Shareholders.

Except as set forth in “Item 6. Directors, Senior Management and Employees—E. Share Ownership,” to the best of our knowledge, no other person who we know beneficially owns 5% or more of the Company’s ordinary shares outstanding as of February 28, 2019, the latest practicable date for inclusion in this annual report. None of our shareholders has different voting rights from other shareholders. Other than as described herein, to the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any natural person or legal persons, severally or jointly, and we are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

B. Related Party Transactions.

The following is a summary description of the material terms of those transactions with related parties to which we, or our subsidiaries, are party and which were in effect since January 1, 2018.

Financing Agreement with GRD

We have provided financing to GRD from time to time, pursuant to which the Company and GRD have executed several capital notes for an aggregate outstanding principal amount of $121.8 million. The par value of such notes is in NIS, and they bear no interest nor repayment date; provided, however, that no repayment shall be made before the fifth anniversary from the issuance date of each note.

Agreements with Directors and Officers

Employment and Consulting Agreements. We have entered into written employment or consulting agreements with certain of our Office Holders. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant Office Holder, during which time the Office Holder will continue to receive base salary and benefits. We have also entered into customary non-competition, confidentiality of information and ownership of inventions arrangements with these Office Holders. However, the enforceability of the noncompetition provisions may be limited under applicable law.

Options. Since our inception, we have granted options to purchase our ordinary shares to certain of our Office Holders. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. See also “Item 6. Directors, Senior Management and Employees—E. Share Ownership”. We describe our 2013 Plan under “Item 6. Directors, Senior Management and Employees—B. Compensation—2013 Incentive Share Option Plan.” If the relationship between us and an Office Holder is terminated except for “cause” (as defined in the 2013 Plan and/or the applicable option award agreement), options that are vested will generally remain exercisable for 90 days after such termination; provided, however, that prior to the date of such termination, our remuneration committee may authorize an extension of the terms of all or part of the vested options beyond the date of such termination for a period not to exceed the period during which the options by their terms would otherwise have been exercisable, and provided further that the vested options may lose their status as incentive stock options and/or approved 102 options if such extension extends beyond the maximum extension authorized by the Ordinance or the Code, as applicable.

RSUs. We have granted RSUs to certain of our Office Holders. Such award agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. See also "Item 6. Directors, Senior Management and Employees—E. Share Ownership." We describe our 2013 Plan under "Item 6. Directors, Senior Management and Employees—B. Compensation—2013 Incentive Share Option Plan." If the relationship between us and an Office Holder is terminated, RSUs that are vested shall be settled in accordance with the settlement schedule set forth in the applicable award agreement.

Marshall Heinberg. Prior to joining our Board in October 2018, Mr. Heinberg provided consulting services to us through MAH Associates, LLC, or MAH since 2013. During 2018, we paid MAH aggregate consulting fees of $167,520 up to the time he joined the Board.

C. Interests of Experts and Counsel.

Not applicable.

ITEM 8. Financial Information.

A. Consolidated Financial Statements and Other Financial Information.

See "Item 18. Financial Statements" for a list of all financial statements filed as part of this annual report.

Legal Matters

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

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. See “Item 10. Additional Information—E. Taxation—Certain Israeli Tax Considerations” for additional information.

B. Significant Changes.

No significant changes with respect to our consolidated financial statements have occurred since December 31, 2017.

ITEM 9. The Offer and Listing.

A.4 Offer and Listing Details

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.

B. Plan of Distribution

Not applicable.

C. Market for Ordinary Shares

Our ordinary shares have been quoted on the NASDAQ Capital Market since March 18, 2014 under the symbol “GLMD.”

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the issue

Not applicable.

ITEM 10. Additional Information.

A. Share Capital.

Not applicable.

B. Memorandum and Articles of Association.

Our registration number is 51-495351-2. At the 2014 annual general meeting of shareholders, our shareholders adopted our Articles, which became effective on the consummation of our initial public offering in the United States in March 2014. Under Section 2 of our Articles, the purpose of the Company is to engage in any lawful activity.

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

Election of Directors

Our Board consists of three classes of directors (not including external directors who do not form part of any class), with one class being elected each year by shareholders at the Company's annual general meeting for a term of approximately three years. In accordance with our Articles, directors so elected cannot be removed from office by the shareholders until the expiration of their term of office. Ordinary shares do not have cumulative voting rights. As a result, the holders of ordinary shares that represent a simple majority of the voting power represented at a shareholders' meeting and voting at the meeting have the power to elect all of the directors put forward for election, subject to specific requirements under the Companies Law with respect to the election of external directors. For further information as to these appointments, see "Item 6—Directors, Senior Management and Employees—C. Board Practices."

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

Our Articles provide that a director may, by written notice to the Company, appoint another person to serve as an alternate director provided that such appointment is approved by a majority of the directors then in office, and that such appointing director may remove such alternate director. Any alternate director shall be entitled to notice of meetings of the Board and of relevant committees and to attend and vote accordingly, except that the alternate has no standing at any meeting at which the appointing director is present or at which the appointing director is not entitled to participate as provided in the Companies Law. A person who is not qualified to be appointed as a director, or a person who already serves as a director or an alternate director, may not be appointed as an alternate director.

Unless the appointing director limits the time or scope of the appointment, the appointment is effective for all purposes until the earlier of (i) the appointing director ceasing to be a director; (ii) the appointing director terminating the appointment; or (iii) the occurrence, with respect to the alternate, of any of the circumstances under which a director shall vacate his or her office. The appointment of an alternate director does not in itself diminish the responsibility of the appointing director as a director. An alternate director is solely responsible for his or her actions and omissions and is not deemed an agent of the appointing director. Under the Companies Law, external directors cannot generally appoint alternate directors, and a person who is not qualified to be appointed as an "independent" director may not be appointed as an alternate to an independent director. See "Item 6—Directors, Senior Management and Employees—C. Board Practices." At present, there are no effective appointments of alternate directors for our Board.

Borrowing Powers

Our Board may from time to time, and at its reasonable discretion, borrow or secure the payment of any sum or sums of money for reasonable Company purposes. The directors may raise or secure the repayment of such sum or sums in such manner, at such times and upon such terms and conditions in all respects as they see fit and, in particular, by issuing bonds, perpetual or redeemable debentures, debenture stock or any mortgages, charges or other securities on the undertaking of the whole or any part of the property of the Company, both present and future, including current uncalled capital and called but unpaid capital.

For discussions relating to certain compensation-related requirements of the Companies Law, external directors and financial experts, committees of the Board, and exculpation and indemnification of directors and officers, see "Item 6 - Directors, Senior Management and Employees."

Fiduciary Duties of Directors and Executive Officers

The Companies Law codifies the fiduciary duties that Office Holders owe to a company. Each person listed in the table under "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management" is an Office Holder under the Companies Law.

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

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

- all other important information pertaining to these actions.

The duty of loyalty requires an Office Holder to act in good faith and for the benefit of a company, and includes a duty to:

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

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an Office Holder promptly disclose to the board of directors any personal interest that he or she may have concerning any existing or proposed transaction with a company, as well as any substantial information or document with respect thereof. An interested Office Holder's disclosure must be made promptly and, in any event, no later than the first meeting of the board of directors at which the transaction is considered.

Under the Companies Law, a "personal interest includes an interest of any person in an action or transaction of a company, including a personal interest of one's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in a company. A personal interest furthermore includes the personal interest of a person for whom the Office Holder holds a voting proxy or the interest of the Office Holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy, even if such shareholder itself has no personal interest in the approval of the matter. An Office Holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of a relative of such Office Holder in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, an extraordinary transaction is defined as any of the following:

- a transaction other than in the ordinary course of business;

- a transaction that is not on market terms; or

- a transaction that may have a material impact on a company's profitability, assets or liabilities.

Approval Procedure

If an Office Holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the articles of association of a company provide for a different method of approval. Our Articles do not provide for any such different method of approval. Further, so long as an Office Holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the Office Holder that would otherwise be deemed a breach of the duty of loyalty. However, a company may not approve a transaction or action that is adverse to such company's interest or that is not performed by the Office Holder in good faith. Approval first by a company's audit committee and subsequently by the board of directors is required for an extraordinary transaction in which an Office Holder has a personal interest. Arrangements regarding the Office Holders' terms of office and employment (which includes compensation, indemnification or insurance) generally require the approval of the remuneration committee, board of directors and, in certain circumstances, the shareholders, in that order, and must generally be consistent with the Company's Compensation Policy, as described under see "Item 6—Directors, Senior Management and Employees—B. Compensation."

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

Transactions with Controlling Shareholders

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a controlling shareholder or an officer who is a controlling shareholder of a company, a controlling shareholder also includes any shareholder who holds 25% or more of the voting rights if no other shareholder holds more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be a single shareholder and may be deemed a controlling shareholder for the purpose of approving such transaction.

Extraordinary Transactions, including private placement transactions, with a controlling shareholder or in which a controlling shareholder has a personal interest, and engagements with a controlling shareholder or his or her relative, directly or indirectly, including through a corporation under his or her control, regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder or an employee of the company, regarding his or her terms of service or employment, require the approval of the audit committee or remuneration committee, the board of directors and the shareholders of a company by a Special Majority, in that order.

Arrangements regarding the terms of office and employment of a controlling shareholder who is an Office Holder, and the terms of employment of a controlling shareholder who is an employee of a company, require the approval of the remuneration committee, board of directors and the shareholders by a Special Majority, in that order, as further described above under "Item 6—Directors, Senior Management and Employees—B. Compensation" with respect to Office Holders' compensation.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Dividends and Dividend Policy

Dividends may be distributed only out of profits available for dividends as determined by the Companies Law, provided that there is no reasonable concern that the distribution will prevent the Company from being able to meet its existing and anticipated obligations when they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally

available for distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it is convinced that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

Generally, under the Companies Law, the decision to distribute dividends and the amount to be distributed is made by a company's board of directors. The Articles provide that the Board may from time to time declare, and cause the Company to pay, such dividends as may appear to it to be justified by the profits of the Company and that the Board has the authority to determine the time for payment of such dividends and the record date for determining the shareholders entitled to receive such dividends, provided the date is not before the date of the resolution to distribute the dividend. Declaration of dividends does not require shareholder approval.

Pursuant to our Articles, subject to the rights of holders of shares with limited or preferred rights, ordinary shares shall confer upon the holders thereof equal rights to receive dividends and to participate in the distribution of the assets of the Company upon its winding-up, in proportion to the amount paid up or credited as paid up on account of the nominal value of the shares held by them respectively and in respect of which such dividends are being paid or such distribution is being made, without regard to any premium paid in excess of the nominal value, if any.

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

Payment of dividends may also be subject to Israeli withholding taxes. See "Taxation — Israeli Tax Considerations" for additional information.

Transfer of Shares

Ordinary shares which have been fully paid-up are transferable by submission of a proper instrument of transfer to the Company or its transfer agent together with the certificate of the shares to be transferred and such other evidence, if any, as the directors may require to prove the rights of the intending transferor in the transferred shares.

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

Shareholder Meetings

Our Articles provide that an annual general meeting must be held at least once in every calendar year, not later than 15 months after the last preceding annual general meeting, at such time and place as may be determined by the Board. The Board may, in its discretion, convene additional shareholder meetings and, pursuant to the Companies Law, must convene a meeting upon the demand of two directors or one quarter of the directors then in office or upon the demand of the holder or holders of 5% of the Company's issued share capital and 1% of its voting rights or upon the demand of the holder or holders of 5% of its voting rights. All demands for shareholder meetings must set forth the items to be considered at that meeting. Pursuant to the Companies Law, the holder or holders of 1% of the Company's voting rights may request the inclusion of an item on the agenda of a future shareholder meeting, provided the item is appropriate for discussion at a shareholder meeting.

The agenda for a shareholder meeting is determined by the Board and must include matters in respect of which the convening of a shareholder meeting was demanded and any matter requested to be included by holder(s) of 1% of the Company's voting rights. According to regulations promulgated pursuant to the Companies Law and governing the terms of notice and publication of shareholder meetings of public companies, or the General Meeting Regulations, holder(s) of one percent or more of the Company's voting rights may propose any matter appropriate for deliberation at a shareholder meeting to be included on the agenda of a shareholder meeting, generally by submitting a proposal within seven days of publicizing the convening of a shareholder meeting, or, if the Company publishes a preliminary notice at least 21 days prior to publicizing the convening of a meeting (stating its intention to convene such meeting and the agenda thereof), within 14 days of such preliminary notice. Any such proposal must further comply with the information requirements under applicable law and the Articles.

Pursuant to the Companies Law and regulations promulgated thereunder with respect to the convening of general meetings in a public company, shareholder meetings generally require prior notice of not less than 21 days, and for certain matters specified in the Companies Law, not less than 35 days. The function of the annual general meeting is to elect directors in accordance with the Articles, receive and consider the profit and loss account, the balance sheet and the ordinary reports and accounts of the directors and auditors, appoint auditors and fix their remuneration and transact any other business which under the Articles or applicable law may be transacted by the shareholders of a company in general meeting.

Our Articles determine that the quorum required for either an annual (regular) or an extraordinary (special) general meeting of shareholders consists of at least two shareholders present in person or by proxy holding shares comprising in the aggregate more than 33.33% of the voting rights of the Company. If a meeting is convened by the Board upon the demand of shareholders or upon the demand of less than 50% of the directors then in office or directly by such shareholders or directors and no quorum is present within half an hour from the time appointed, it shall be cancelled. If a meeting is otherwise called and no quorum is present within such time, the meeting is adjourned to the same day one week later at the same time and place or at such other time and place as the Board may determine and specify in the notice of the general meeting and it shall not be necessary to give notice of such adjournment. If a quorum is not present within half an hour from the time stated for such adjourned meeting, any two shareholders present in person or by proxy at such meeting shall constitute a quorum even if, between them, they represent shares conferring 33.33% or less of the voting rights of the Company.

Generally, under the Companies Law and the Articles, shareholder resolutions are deemed adopted if approved by the holders of a simple majority of the voting rights represented at a meeting and voting unless a different majority is required by law or pursuant to the Articles. The Companies Law provides that resolutions on certain matters, such as amending a company’s articles of association, assuming the authority of the board of directors in certain circumstances, appointing auditors, appointing external directors, approving certain transactions, increasing or decreasing the registered share capital and approving most mergers must be made by the shareholders at a general meeting. A company may determine in its articles of association certain additional matters in respect of which resolutions by the shareholders in a general meeting will be required.

Access to Corporate Records

Under the Companies Law, all shareholders generally have the right to review minutes of our general meetings, our shareholder register and register of significant shareholders (as defined in the Companies Law), our articles of association, our financial statements, other documents as provided in the Companies Law, and any document we are required by law to file publicly with the Israeli Companies Registrar. Any shareholder who specifies the purpose of its request may request to review any document in our possession that relates to: (i) any action or transaction with a related party which requires shareholder approval under the Companies Law; or (ii) the approval, by the board of directors, of an action in which an office holder has a personal interest. We may deny a request to review a document if we determine that the request was not made in good faith, or if such denial is necessary to protect our interest or protect a trade secret or patent.

Shareholder Duties

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

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- approval of interested party transactions and acts of Office Holders that require shareholder approval.

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

Certain shareholders have a further duty of fairness toward a company. These shareholders include any controlling shareholder, any shareholder who knows that it has the power to determine the outcome of a shareholder vote or a shareholder class vote and any shareholder who has the power to appoint or to prevent the appointment of an Office Holder of the company or other power towards the company. The Companies Law does not define the substance of

this duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

Mergers and Acquisitions under Israeli Law

(i) Merger

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

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

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

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

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

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

(ii) Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This rule does not apply if there is already another holder of 25% or more of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

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

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

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention. In addition, the board of directors must disclose any personal interest each of member of the board of directors have in the offer or stems therefrom.

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

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them shall refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

(iii) Full Tender Offer

Under the Companies Law, a person may not acquire shares in a public company if, after the acquisition, he will hold more than 90% of the shares or more than 90% of any class of shares of that company, unless a tender offer is made to purchase all of the shares or all of the shares of the particular class. The Companies Law also provides, subject to certain exceptions, that as long as a shareholder in a public company holds more than 90% of the company's shares or of a class of shares, that shareholder shall be precluded from purchasing any additional shares unless tendering an offer to purchase all of the outstanding shares of the company or the applicable class of the shares. If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

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

If the conditions set forth above are not met, the purchaser may not acquire additional shares of the company from shareholders who accepted the tender offer to the extent that following such acquisition, the purchaser would own more than 90% of the company's issued and outstanding share capital.

Anti-Takeover Measures under Israeli Law

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the date hereof, no preferred shares are authorized under our Articles. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our Articles, which requires the affirmative vote of at least 75% of the voting rights of the Company represented personally or by proxy and voting thereon at a general meeting at which a quorum is present. The convening of the general meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Articles and the Companies Law as described above in "— Shareholder Meetings."

In addition, certain provisions of the Articles may have the effect of rendering more difficult or discouraging an acquisition of the Company deemed undesirable by the Board. The classification of the Board into three classes with terms of approximately three years each, and the requirement under Companies Law to have at least two external directors, who cannot readily be removed from office, may make it more difficult for shareholders who oppose the policies of the Board to remove a majority of the then current directors from office quickly. It may also, in some circumstances, together with the other provisions of the Articles and Israeli law, deter or delay potential future merger, acquisition, tender or takeover offers, proxy contests or changes in control or management of the Company.

Changes in Capital

The registered share capital of the Company is NIS 500,000 divided into 50,000,000 ordinary shares, NIS 0.01 par value per share.

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

Changes in Shareholder Rights

Pursuant to our Articles, if at any time the share capital is divided into different classes of shares, the Company may by shareholder resolution, unless otherwise provided by the terms of issue of the shares of that class, modify, convert, broaden, add or otherwise alter the rights, privileges, advantages, restrictions and provisions related or unrelated at that time to the shares of any class with the sanction of a resolution passed by a simple majority of those present, personally or by proxy, and voting thereon at a separate general meeting of the holders of the shares of that class. Such majority approval is consistent with Israeli law.

C. Material Contracts

For a description of our material agreements relating to our strategic collaborations and research arrangements and other material agreements, please refer to "Item 4.B. Information on the Company—Business Overview—Strategic Collaborations, Research Arrangements and other Material Agreements."

Employment Agreements

See "Item 6. Directors, Senior Management and Employees—B. Compensation".

D. Exchange Controls.

There are no Israeli government laws, decrees, regulations or other legislation that restrict or that affect our export or import of capital, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, or the remittance of dividends, interest or other payments to non-resident holders of our securities, except for ownership by nationals of certain countries that are, or have been, declared as enemies of Israel or otherwise as set forth under "Item 10. Additional Information—E. Taxation."

E. Taxation.

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

Certain Israeli Tax Considerations

The following is a brief summary of the material Israeli income tax laws applicable to us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include residents of Israel or investors in securities who are subject to special tax

regimes not covered in this discussion. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. This summary is based on laws and regulations in effect as of the date hereof and does not take into account possible future amendments which may be under consideration.

General Corporate Tax Structure in Israel

Israeli resident companies (as defined below), such as the Company, are generally subject to corporate tax at the rate of 23% on their taxable income, as of January 1, 2018 (24% in 2017). However, the effective tax rate payable by a company that derives income from a Preferred Enterprise or a Technology Enterprise, as discussed below, may be considerably less.

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

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, which we refer to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies," which are defined as Israeli resident-companies which were incorporated in Israel, of which 90% or more of their income in any tax year, other than income from certain government loans, is derived from an "Industrial Enterprise" that it owns and located in Israel. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production. Eligibility for benefits under the Industry Encouragement Law is not contingent upon approval of any governmental authority.

The following tax benefits, among others, are available to Industrial Companies:

- amortization over an eight year period of the cost of purchasing a patent, rights to use a patent and rights to know-how, which are used for the development or advancement of the company, commencing in the year in which such rights were first exercised;

- under limited conditions, an election to file consolidated tax returns with related Industrial Companies controlled by it; and

- deductions of expenses related to a public offering in equal amounts over a three year period commencing on the year of the offering.

We believe that we qualify as an “Industrial Company” within the meaning of the Industry Encouragement Law. There can be no assurance that we will continue to qualify as an Industrial Company in the future or that the benefits described above will be available to us at all.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, which we refer to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) by "Industrial Enterprises” (as defined under the Investment Law). Generally, an investment program that is implemented in accordance with the provisions of the Investment Law, is entitled to benefits. These benefits may include cash grants from the Israeli government and tax benefits, based upon, among other things, the geographic location in Israel of the facility in which the investment is made. In order to qualify for these incentives, an Approved Enterprise, a Beneficiary Enterprise or a Preferred Enterprise is required to comply with the requirements of the Investment Law.

The Investment Law was significantly amended effective April 1, 2005, further amended as of January 1, 2011, or the 2011 Amendment, and as of January 1, 2017, or the 2017 Amendment. The 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment. However, companies entitled to benefits under the Investment Law as in effect up to January 1, 2011 were entitled to choose to continue to enjoy such benefits, provided that certain conditions are met, or elect instead, irrevocably, to forego such benefits and elect the benefits of the 2011 Amendment. The 2017 Amendment introduces new benefits for Technological Enterprises, alongside the existing tax benefits.

The following discussion is a summary of the Investment Law following its most recent amendments:

Tax Benefits Under the 2011 Amendment

The 2011 Amendment canceled the availability of the benefits granted to Industrial Companies under the Investment Law prior to 2011 and, instead, introduced new benefits for income generated by a "Preferred Company" through its "Preferred Enterprise" (as such terms are defined in the Investment Law) as of January 1, 2011.

The definition of a Preferred Company includes a company incorporated in Israel that is not fully owned by a governmental entity, and that has, among other things, a Preferred Enterprise and is controlled and managed from Israel. Pursuant to the 2011 Amendment , beginning in 2014 and in each year thereafter until 2016, a Preferred Company may only be entitled to a reduced corporate tax rate of 16% with respect to its preferred income derived by its Preferred Enterprise, unless the Preferred Enterprise is located in a specified development zone, in which case the rate will be 9%. Pursuant to the 2017 Amendment, in 2017 and thereafter, the corporate tax rate for Preferred Enterprise which is located in a specified development zone was reduced to 7.5%, while the reduced corporate tax rate for other development zones remains 16%. Income derived by a Preferred Company from a "Special Preferred Enterprise" (as such term is defined in the Investment Law) would be entitled, during a benefit period of ten years, to further reduced tax rates of 8%, or 5% if the Special Preferred Enterprise is located in a certain development zone. As of January 1, 2017, the definition for 'Special Preferred Enterprise' includes less stringent conditions.

As of January 1, 2014, dividends paid out of income attributed to a Preferred Enterprise or to a Special Preferred Enterprise are generally subject to withholding tax at source at the rate of 20% unless a lower tax rate is provided under an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply). In 2017-2019 dividends paid out of preferred income attributed to a Special Preferred Enterprise, directly to a foreign parent company, are subject to withholding tax at source at the rate of 5% (temporary provisions).

New Tax benefits under the 2017 Amendment

The 2017 Amendment was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017. The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in development zone A. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million (approximately $56 million), and the sale receives prior approval from the National Authority for Technological Innovation (referred to as NATI).

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by an Israeli company or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million (approximately $144 million) will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are subject to withholding tax at source at the rate of 20%, or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. If such dividends are distributed to a foreign parent company holding at least 90% of the shares of the distributing company and other conditions are met, the withholding tax rate will be 4% (or a lower rate under a tax treaty, if applicable, subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate).

After examining the impact of the 2017 Amendment, we submitted a request to receive a tax ruling from the Israel Tax Authority to be recognized as a Preferred Technology Enterprise and recently we received a tax ruling from the

Israel Tax Authority granting GRD a Preferred Technology Enterprise status, subject to terms and conditions determined in the tax ruling.

Taxation of Our Israeli Individual Shareholders on Receipt of Dividends

Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of 25%, or 30% if the recipient of such dividend is a Substantial Shareholder (as defined below) at the time of distribution or at any time during the preceding 12 month period. However, dividends distributed from taxable income accrued from Preferred Enterprise to Israeli individuals are subject to withholding tax at the rate of 20%. However, if such dividends are distributed to an Israeli company, no tax is imposed (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for an exemption) will apply). An average rate will be set in case the dividend is distributed from mixed types of income (regular and preferred income).

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

With respect to individuals, the term “Israeli resident” is generally defined under Israeli tax legislation as a person whose center of life is in Israel. The Israeli Tax Ordinance (as amended by Amendment Law No. 132 of 2002), states that in order to determine the center of life of an individual, consideration will be given to the individual’s family, economic and social connections, including: (i) place of permanent residence; (ii) place of residential dwelling of the individual and the individual’s immediate family; (iii) place of the individual’s regular or permanent occupation or the place of his or her permanent employment; (iv) place of the individual’s active and substantial economic interests; (v) place of the individual’s activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (i) the individual was present in Israel for 183 days or more in the tax year; or (ii) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual’s presence in Israel in that tax year and the two previous tax years is 425 days or more. Such presumption may be rebutted either by the individual or by the assessing officer.

Payers of dividends on our ordinary shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, to withhold tax upon the distribution of dividend at the rate of 25% (whether the recipient is a Substantial Shareholder or not), so long as the shares are registered with a nominee company.

Taxation of Israeli Resident Corporations on Payment of Dividends

Israeli resident corporations are generally exempt from Israeli corporate income tax with respect to dividends paid on ordinary shares of Israeli resident corporations as long as the profits out of which the dividends were paid were derived in Israel.

Capital Gains Taxes Applicable to Israeli Resident Shareholders

The income tax rate applicable to real capital gains derived by an Israeli individual resident from the sale of shares that were purchased after January 1, 2012, whether listed on a stock exchange or not, is 25%. However, if such shareholder is considered a Substantial Shareholder at the time of sale or at any time during the preceding 12 month period and/or claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares, such gain will be taxed at the rate of 30%.

Moreover, capital gains derived by an individual shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income, are taxed in Israel at their marginal rates applicable to business income (up to 50% in 2017 and 2018, including Excess Tax as detailed below).

At the sale of securities traded on a stock exchange, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Tax Ordinance and regulations promulgated thereunder, the aforementioned return is not required to be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 25% (or 30% for individuals, if such person is a Substantial Shareholder at the time he or she receives the dividend or on any date in the 12 months preceding such date), or 20% if the dividend is distributed from income attributed to Preferred Enterprise unless a lower rate is provided under an applicable tax treaty between Israel and the shareholder's country of residence and provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

A non-Israeli resident who has dividend income derived from or accrued in Israel, from which the full amount of tax was withheld at source, is generally exempt from the duty to file tax returns in Israel in respect of such income; provided that (i) such income was not derived from a business conducted in Israel by the taxpayer and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

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

Payers of dividends on our ordinary shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, to withhold tax upon the distribution of dividend at the rate of 25% (whether the recipient is a Substantial Shareholder or not), so long as the shares are registered with a nominee company.

Capital Gains Income Taxes Applicable to Non-Israeli Shareholders

Non-Israeli resident shareholders are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such shareholders did not acquire their shares prior to January 1, 2009 or acquired their shares after the Company was listed for trading on NASDAQ and such gains were not derived from a permanent business or business activity of such shareholders in Israel. These provisions dealing with capital gain are not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be business income. However, non-Israeli corporations will not be entitled to the foregoing exemptions if an Israeli resident (i) has a controlling interest of more than 25% in such non-Israeli corporation or (ii) is the beneficiary of or is entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

In addition, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the U.S.-Israel Tax Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the ordinary shares as a capital asset and is entitled to claim the benefits afforded to such a resident by the U.S.-Israel Tax Treaty, or a Treaty U.S. Resident, is generally exempt from Israeli capital gains tax unless: (i) such Treaty U.S. Resident is an individual and was present in Israel for 183 days or more in the aggregate during the relevant taxable year; (ii) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of our voting power of the Company during any part of the 12 month period preceding such sale, exchange or disposition, subject to certain conditions; (iii) the capital gains arising from such sale, exchange or disposition are attributable to a permanent establishment of the Treaty U.S. Resident maintained in Israel, subject to certain conditions; (iv) the capital gains arising from such sale, exchange or disposition is attributed to real estate located in Israel; or (v) the capital gains arising from such sale, exchange or disposition is attributed to royalties. In any such case, the sale, exchange or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable. However, under the U.S.-Israel Tax Treaty, such Treaty U.S. Resident would be permitted to claim a credit for such taxes against U.S. federal income tax imposed on any gain from such sale, exchange or disposition, under the circumstances and subject to the limitations specified in the U.S.-Israel Income Tax Treaty.

Regardless of whether shareholders may be liable for Israeli income tax on the sale of our ordinary shares, the payment of the consideration may be subject to withholding of Israeli tax at the source. Accordingly, shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale. Specifically, in transactions involving a sale of all of the shares of an Israeli resident company, in the form of a merger or otherwise, the Israel Tax Authority may require from shareholders who are not liable for Israeli tax to sign declarations in forms specified by this authority or obtain a specific exemption from the Israel Tax Authority to confirm their status as non-Israeli resident, and, in the absence of such declarations or exemptions, may require the purchaser of the shares to withhold taxes at source.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income exceeding a certain threshold (NIS 641,880 for 2018, which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to, dividends, interest and capital gains.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

Pre-Ruling Regarding a Reorganization of Our Corporate Structure

In connection with the Reorganization, as detailed under "Item 4. Information on the Company—Historical Background and Corporate Structure" above, we obtained a pre-ruling from the Israel Tax Authority. The Tax Pre-Ruling confirms that the transfer of shares and assets resulting in the Company as the parent company and 100% equity-owner of GRD, which holds all the Group's intellectual property, including the Company's patent portfolio and GIL, is not taxable pursuant to the provisions of the Israeli Tax Ordinance as long as certain requirements are met. Pursuant to the Tax Pre-Ruling, certain restrictions under the Israeli tax laws were applied to the Company and its subsidiaries, as well as to those shareholders and option holders and other holders of rights in the share capital of the Company (on a diluted basis), who participated in the Reorganization and held such rights immediately after the consummation of the Reorganization, or the Rights Holders. In this section, each of the terms "Rights" and/or "share capital (on a diluted basis)" includes shares, options to purchase shares and any other "right" in "a body of persons" as such term is defined in the Israeli Tax Ordinance. These restrictions generally restrict these entities and Rights Holders from making any disposition of their Rights in the transferred assets and shares for a two-year period following the consummation of the Reorganization, which ended in February 2016, or the Restriction Period. During the Restriction Period, these restrictions included the following:

- Sale or otherwise disposition of our intellectual property, other than out-licensing in the ordinary course of business, was not permitted;

- the Rights Holders immediately following the Reorganization must not have changed. Notwithstanding this restriction, so long as the aggregate holdings of the Rights Holders, collectively, was 51% or more of the total share capital of the Company at any time during the Restriction Period, certain changes in the holding percentages of the Rights Holders might have been permitted during the Restriction Period under the Israeli Tax Ordinance and guidelines issued by the Israel Tax Authorities;

- the Rights Holders may not have sold or otherwise transfer or dispose of more than 10% of their respective Rights, subject to the exemptions and relief detailed below;

- Sale or otherwise transfer or disposition of any of our shares in GHI or GIL, was not permitted; and

- during the two tax years following the end of the year in which the Reorganization was completed we may not have offset losses (whether business or capital losses) incurred in the year in which the Reorganization was completed or in the years preceded that year up to the fair market value of the transferred asset.

In addition, no deduction for tax purposes is allowed in relation to the Reorganization.

If during the Restriction Period, we or the Rights Holders committed a violation, the transfer of shares or other rights and/or assets in connection with the Reorganization will become subject to taxation based on the greater of the transferred assets' fair market value on the day of such violation or taxes that, but for the Tax Pre-Ruling, would be payable in connection with the transfer of such assets and shares at the time of the Reorganization, linked to the Israeli consumer price index linkage differentials and interest from the day of the actual transfer of such assets and shares until the day of payment of such taxes, unless the Israel Tax Authority is satisfied that such violation was a result of special circumstances beyond our control. The Restriction Period ended on February 2016, and to our knowledge, neither we nor any of the Right Holders has committed a violation during the Restriction Period pursuant to the terms and conditions of the Tax Pre Ruling.

Certain U.S. Federal Income Tax Considerations

The following is a general summary of certain material U.S. federal income tax consequences relating to the purchase, ownership and disposition of our ordinary shares by U.S. Holders (as defined below). This summary is based on the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, the income tax treaty between the United States and Israel, or the U.S.-Israel Tax Treaty, and

administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. No ruling has been sought from the IRS with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This summary is no substitute for consultation by prospective investors with their own tax advisors and does not constitute tax advice. This summary applies only to U.S. Holders that hold our ordinary shares as capital assets for U.S. federal income tax purposes (generally, property held for investment) and does not address all of the tax considerations that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (including, without limitation, banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire our ordinary shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons who acquire our ordinary shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, persons that have a “functional currency” other than the U.S. dollar, persons that own (or are deemed to own, indirectly, or by attribution) 10% or more of our shares (by vote or value), or persons that mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift or alternative minimum tax considerations, or any U.S. federal tax consequences other than U.S. federal income tax consequences.

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

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares, the tax treatment of such entity or arrangement treated as a partnership and each person treated as a partner thereof generally will depend upon the status and activities of the entity and such person. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of our ordinary shares.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Holders. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Holders

Distributions. Subject to the discussion below under "Passive Foreign Investment Company," a U.S. Holder that receives a distribution with respect to an ordinary share generally will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Israeli tax withheld from such distribution) when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). Any distributions in excess of our earnings and profits will be applied against and will reduce (but not below zero) the U.S. Holder's tax basis in its ordinary shares, and, to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of our ordinary shares. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that a distribution will be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

As noted above, we do not anticipate paying any cash dividends in the foreseeable future. If we were to pay dividends, we expect to pay such dividends in NIS. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Holder's income at a U.S. dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Holder generally will not recognize a foreign currency gain or loss. However, if the U.S. Holder converts the NIS into U.S. dollars on a later date, the U.S. Holder must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss generally will be ordinary income or loss and will be U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Holder may be credited against the U.S. Holder's U.S. federal income tax liability or, alternatively, may be deducted from the U.S. Holder's taxable income. The election to deduct, rather than credit, foreign taxes, is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Holder or withheld from a U.S. Holder that year. Dividends paid on the ordinary shares generally will constitute income from sources outside the United States and be categorized as "passive category income" or, in the case of some U.S. Holders, as "general category income" for U.S. foreign tax credit purposes. Because the rules governing foreign tax credits are complex, U.S. Holders should consult their own tax advisors regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares will not be eligible for the "dividends-received" deduction generally allowed to corporate U.S. Holders with respect to dividends received from U.S. corporations.

Certain distributions treated as dividends that are received by an individual U.S. Holder from a "qualified foreign corporation" may be classified as "qualified dividend income," — which is generally taxed at the lower applicable long term capital gains rates provided certain holding period and other requirements are satisfied. A non-U.S. corporation (other than a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. As discussed below under "Passive Foreign Investment Company," we believe that we were not a PFIC for our 2018 taxable year. However, we do expect to be a PFIC for the 2019 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we will be a PFIC in 2019 or for any other taxable year. Our ordinary shares will generally be considered to be readily tradable on an established securities market in the United States if they are listed on the Nasdaq Capital Market, as we intend our ordinary shares will be. U.S. Holders should consult their own tax advisors regarding the availability of the lower rate for dividends paid with respect to our ordinary shares.

The additional 3.8% "net investment income tax" (described below) may apply to dividends received by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

Sale, Exchange or Other Taxable Disposition of Ordinary Shares. Subject to the discussion under "Passive Foreign Investment Company" below, a U.S. Holder generally will recognize capital gain or loss upon the sale, exchange, or other taxable disposition of our ordinary shares in an amount equal to the difference between the amount realized on the sale, exchange, or other taxable disposition and the U.S. Holder's adjusted tax basis (determined under U.S. federal income tax rules) in such ordinary shares. This capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period in our ordinary shares exceeds one year. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 20%) will apply to individual U.S. Holders. The deductibility of capital losses is subject to limitations. The gain or loss generally will be income or loss from sources within the United States for U.S. foreign tax credit purposes, subject to certain possible exceptions under the U.S.-Israel Tax Treaty. The additional 3.8% "net investment income tax" (described below) may apply to gains recognized upon the sale, exchange, or other taxable disposition of our ordinary shares by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

Passive Foreign Investment Company. In general, a non-U.S. corporation will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is "passive income," or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. Assets that produce or are held for the production of passive income include cash, even if held as working capital or raised in a public offering, marketable debt securities and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

A foreign corporation's PFIC status is an annual determination that is based on tests that are factual in nature, and our status for any year will depend on our income, assets, and activities for such year. Based upon our review of our financial data, we believe that we were not a PFIC for our 2018 taxable year and we expect to be a PFIC for the 2019 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we will be a PFIC in 2019 or for any other taxable year.

Default PFIC Rules. If we are a PFIC for any tax year, a U.S. Holder who does not make a timely "qualified electing fund" election, or "QEF election" (as discussed below, we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a QEF election), or a mark-to-market election (as described below), referred to in this summary as a "Non-Electing U.S. Holder," will be subject to special rules with respect to (i) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Holder on the ordinary shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Holder in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Holder's holding period for the ordinary shares), and (ii) any gain realized on the sale or other disposition of such ordinary shares. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Holder's holding period for such ordinary shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Holder who is an individual dies while owning our ordinary shares, the Non-Electing U.S. Holder's successor would be ineligible to receive a step-up in tax basis of such ordinary shares. Non-Electing U.S. Holders should consult their tax advisors regarding the application of the "net investment income tax" (described below) to their specific situation.

To the extent a distribution on our ordinary shares does not constitute an excess distribution to a Non-Electing U.S. Holder, such Non-Electing U.S. Holder generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current and/or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "Taxation of U.S. Holders—Distributions." Each U.S. Holder is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Holder, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Holder is treated as a direct or indirect Non-Electing U.S. Holder even if we are not a PFIC for such years. A U.S. Holder is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Code Section 1298(b)(1) (which will be taxed under the adverse tax rules described above).

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. If we are classified as a PFIC, under attribution rules, U.S. Holders will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the ordinary shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such ordinary shares or the deemed receipt of such distribution by the U.S. Holder, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Holder will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Holder is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

QEF Election. Certain adverse consequences of PFIC status can be mitigated if a U.S. Holder makes a QEF election. Generally, a shareholder making the QEF election is required for each taxable year to include in income a pro rata share of the ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election.

Mark-to-Market Election. Alternatively, if our ordinary shares are treated as "marketable stock," a U.S. Holder would be allowed to make a "mark-to-market" election with respect to our ordinary shares, provided the U.S. Holder completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Holder generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of our ordinary shares at the end of the taxable year over such holder's adjusted tax basis in such ordinary shares. The U.S. Holder would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Holder's adjusted tax basis in our ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to- market election. A U.S. Holder's tax

basis in our ordinary shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Holder, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. To be marketable stock, our ordinary shares must be regularly traded on a qualifying exchange (i) in the United States that is registered with the SEC or a national market system established pursuant to the Exchange Act or (ii) outside the United States that is properly regulated and meets certain trading, listing, financial disclosure and other requirements. Our ordinary shares are expected to constitute "marketable stock" as long as they remain listed on the Nasdaq Capital Market and are regularly traded.

A mark-to-market election will not apply to our ordinary shares held by a U.S. Holder for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Holder is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares.

Each U.S. Holder should consult its own tax adviser with respect to the applicability of the "net investment income tax" (discussed below) where a mark-to-market election is in effect.

In addition, U.S. Holders should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of ordinary shares in a PFIC, including IRS Form 8621, Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund.

The U.S. federal income tax rules relating to PFICs, QEF elections, and mark-to market elections are complex. U.S. Holders are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of our ordinary shares, any elections available with respect to such ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of our ordinary shares.

Certain Reporting Requirements

Certain U.S. Holders may be required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Holder and us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. See the discussion regarding Form 8621, Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, above.

In addition, certain U.S. Holders must report information on IRS Form 8938, Statement of Specified Foreign Financial Assets, with respect to their investments in certain "specified foreign financial assets," which would include an investment in our ordinary shares, if the aggregate value of all of those assets exceeds $50,000 on the last day of the taxable year (and in some circumstances, a higher threshold). This reporting requirement applies to individuals and certain U.S. entities.

U.S. Holders who fail to report required information could become subject to substantial penalties. U.S. Holders should consult their tax advisors regarding the possible implications of these reporting requirements arising from their investment in our ordinary shares.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or proceeds on the disposition of our ordinary shares paid within the United States (and, in certain cases, outside the United States) to U.S. Holders other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently

at 24%) may apply to such amounts if the U.S. Holder fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Holders who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Holder's U.S. federal income tax liability and such U.S. Holder may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Medicare Tax on Investment Income

Certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax, or "net investment income tax," on unearned income. For individuals, the additional net investment income tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes, among other things, passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Holders are urged to consult their own tax advisors regarding the implications of the additional net investment income tax resulting from their ownership and disposition of our ordinary shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES RELATING TO THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

F. Dividends and Paying Agents.

Not applicable.

G. Statements by Experts.

Not applicable.

H. Documents on Display.

The SEC maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. You may read and copy this annual report, including the related exhibits and schedules, and any document we file with the SEC at http://www.sec.gov.

As a "foreign private issuer," we are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements file reports with the SEC. Those other reports or other information may be inspected without charge at the locations described above. As a "foreign private issuer," we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act with respect to their purchases and sales of ordinary shares. Furthermore, as a "foreign private issuer," we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act.

We maintain a corporate website at http://www.galmedpharma.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this annual report and does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

I. Subsidiary Information.

Not applicable.

ITEM 11. Quantitative and Qualitative Disclosures About Market Risk.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the Euro and NIS mainly against the U.S. dollar because a large portion of our expenses are denominated in Euros and NIS. Our Euro expenses consist principally of payments made to sub-contractors and consultants for pre-clinical studies, clinical trials and other research and development activities. Our NIS expenses consist principally of payments made to employees, subcontractors and consultants for pre-clinical studies, clinical trials, professional services, other research and development activities and general and administrative activities. We anticipate that a large portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. Our financial position, results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. Our results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. Approximately 31% of our expected expenses are denominated in NIS. Changes of 5% and 10% in the U.S. dollar to NIS exchange rate will increase/decrease our operation expenses by 1.55% and 3.1%, respectively. Approximately 20% of our expected expenses are denominated in Euros. Changes of 5% and 10% in the U.S. dollar to Euro exchange rate will increase/decrease our operation expenses by 1.0% and 2.0%, respectively. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

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

Interest Rate Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and investment securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investment securities. If a 10% change in interest rates were to have occurred on December 31, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Liquidity

We do not believe that our cash and cash equivalents and available for sale investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents and available for sale investments do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

ITEM 12. Description of Securities Other Than Equity Securities.

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

Not applicable.

PART II

ITEM 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

Not applicable.

ITEM 15. Controls and Procedures.

Disclosure Controls and Procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed in this annual report and filed with the SEC is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within our Company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our President and Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d)-15(e) of the Exchange Act) as of the end of the period covered by this annual report are effective at such reasonable assurance level.

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Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transaction and dispositions of the assets of the company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on that assessment, our management concluded that as of December 31, 2018, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal controls over financial reporting because the JOBS Act provides us with an exemption from that requirement, as we qualify as an emerging growth company.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. Audit Committee Financial Expert.

Our Board has determined that Ms. Yaron-Eldar qualifies as an audit committee financial expert pursuant to the applicable SEC rules and that Ms. Yaron-Eldar is "independent" in accordance with the Nasdaq Capital Market corporate governance requirements. For information relating to Ms. Yaron-Eldar qualifications and experience, see "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management."

ITEM 16B. Code of Ethics.

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our President and Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC and as required by the Nasdaq Listing Rules, which refers to Section 406(c) of the Sarbanes-Oxley Act. Section 406(c) of the Sarbanes-Oxley Act provides that a "code of ethics" means such standards as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the issuer; and (iii) compliance with applicable governmental rules and regulation.

The full text of the Code of Business Conduct and Ethics is posted on our website at www.galmedpharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We will provide a copy of such code of ethics without charge upon request by mail or by telephone. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Business Conduct and Ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC.

ITEM 16C. Principal Accountant Fees and Services.

Brightman Almagor Zohar & Co., Member of Deloitte Touche Tohmatsu Limited, an independent registered public accounting firm, served as our independent public accountants for the fiscal years ended December 31, 2018 and 2017, for which audited financial statements appear in this annual report.

The following table presents the aggregate fees for professional services rendered by such accountants to us during their respective term as our principal accountants in 2018 and 2017.

	2018 (US$ in thousands)	2017 (US$ in thousands)
Audit Fees (1)	60	60
Audit-Related fees (2)	48	35
Tax Fees (3)	0	17
Total	108	112

(1) Includes professional services rendered in connection with the audit of our annual financial statements and the review of our interim financial statements.

(2) Audit related services consist of services that were reasonably related to the performance of the audit or reviews of our financial statements and not included under “Audit Fees” above, including, principally, providing consents for registration statement filings.

(3) Tax fees consist of consulting services related to a tax ruling.

Audit Committee Pre-Approval Policies and Procedures

One of our audit committee's main roles is to assist the board of directors in fulfilling its responsibility for oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company. The audit committee oversees the appointment, compensation, and oversight of the public accounting firm engaged to prepare or issue an audit report on the financial statements of the Company. Our Board has delegated to the audit committee the power to pre-approve non-auditing services rendered by the Company's independent auditors without the need for further approval by the board of directors. As such, our audit committee have adopted a pre-approval policy for the engagement of our independent registered public accounting firm to perform certain audit and non-audit services. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the audit committee pre-approves annually a list of specific audit and non-audit services in the categories of audit services, audit-related services, tax services and other services that may be performed by our independent registered public accounting firm. The last pre-approval policy was adopted by our audit committee on March 10, 2019 for a period of twelve months. Since its establishment in May 2014, the audit committee has approved all of the audit-related fees, tax fees and all other fees. If a type of service that is to be provided by our auditors has not received such general pre-approval, it will require specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in applicable SEC rules.

ITEM 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

ITEM 16F. Change in Registrant's Certifying Accountant.

Not applicable.

ITEM 16G. Corporate Governance.

Our shares are listed on the Nasdaq Capital Market under the symbol "GLMD." In addition to the corporate governance requirements of the Sarbanes-Oxley Act and the related rules implemented by the SEC, we must comply with the Nasdaq Listing Rules. Under those Nasdaq Listing Rules, we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Listing Rules for U.S. domestic issuers.

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

- *Distribution of certain reports to shareholders*. As opposed to the Nasdaq Listing Rules, which require listed issuers to make certain reports, such as annual reports, interim reports and quarterly reports, available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders, but to make such reports available through a public website. In addition to making such reports available on a public website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules. See "Item 10. Additional Information—Documents on Display" for a description of our Exchange Act reporting obligations.

- *Quorum*. While the Nasdaq Listing Rules require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock be no less than 33.33% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our articles of association provide that a quorum of two or more shareholders holding at least 33.33% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our articles of association with respect to an adjourned meeting consists of any two shareholders present in person or by proxy even if, between them, they represent shares conferring 33.33% or less of the voting rights of the Company.

Nomination of directors. With the exception of our external directors and directors elected by our Board due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following three years from his or her election. See "Item 6. Directors, Senior Management and Employees—C. Board Practices." The nominations for directors, which are presented to our shareholders by our Board, are made by the nominating committee itself, in accordance with the provisions of Nasdaq Capital Market Listing Rule 5605(e), our Articles and the Companies Law. Our Board or one or more shareholders of a company holding at least 1% of the voting power of the company may offer to nominate a currently serving external director for an additional three year term.

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Compensation of officers. We follow the provisions of the Companies Law with respect to matters in connection with the composition and responsibilities of our remuneration committee, Office Holder compensation and any required approval by the shareholders of such compensation. Israeli law and our Articles do not require that the independent members of our Board, or a remuneration committee composed solely of independent members of our Board, determine an executive officer's compensation, as is generally required under the Nasdaq Listing Rules with respect to the Chief Executive Officer and all other executive officers of a company. Instead, remuneration of Office Holders is determined and approved by our remuneration committee, and in general, by our Board as well, and in certain circumstances, by our shareholders, as detailed above. The requirements for shareholder approval of any Office Holder compensation, and the relevant majority or Special Majority for such approval, are all as set forth in the Companies Law. Thus, we seek shareholder approval for all corporate actions with respect to Office Holder compensation requiring such approval under the requirements of the Companies Law, including for our Compensation Policy and for certain Office Holder Compensation, rather than seeking approval for such corporate actions in accordance with Nasdaq Listing Rules. All members of our remuneration committee are independent directors under applicable Nasdaq Capital Market and SEC rules, as affirmatively determined by our Board. See "Item 6. Directors, Senior Management and Employees—B. Compensation."

- *Independent directors.* Although Israeli law does not require that a majority of the directors serving on our Board be "independent," as defined under Nasdaq Capital Market Listing Rule 5605(a)(2), but rather requires we have at least two external directors who meet the requirements of the Companies Law, as described above under "Item 6. Directors, Senior Management and Employees—C. Board Practices—External Directors.", a majority of our Board is independent based on the Nasdaq Capital Market rules. We are required, however, to ensure that all members of our audit committee are "independent" under the applicable Nasdaq Capital Market and SEC criteria for independence (as we cannot exempt ourselves from compliance with that SEC independence requirement, despite our status as a foreign private issuer) and we must also ensure that a majority of the members of our audit committee are "independent directors" as defined in the Companies Law. Our independent director's conduct regularly scheduled meetings at which only such independent directors are present, as required by the Nasdaq Listing Rules. Our Board has affirmatively determined that each of Mr. Nir, Mrs. Yaron-Eldar, Mr. Marth, Dr. Sidransky and Dr. Brosgart qualifies as "independent" under the Nasdaq Capital Market independence standards.

- *Shareholder approval*. We will seek shareholder approval for all corporate actions requiring such approval under requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with Nasdaq Capital Market Listing Rule 5635. In particular, under this Nasdaq Capital Market rule, shareholder approval is generally required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (or via sales by directors, officers or 5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the remuneration committee, board of directors and shareholders are all required, (ii) Extraordinary Transactions with controlling shareholders of publicly held companies, which require the special approval described under "Item 6. Directors, Senior Management and Employees—C. Board Practices—Approval of Related Party Transactions under Israeli Law—Transactions with Controlling Shareholders," and (iii) terms of office

and employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative, which require the special approval described under "Item 6. Directors, Senior Management and Employees—B. Compensation" and "Item 6. Directors, Senior Management and Employees—C. Board Practices—Approval of Related Party Transactions under Israeli Law." In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies. See also "Compensation of officers" above.

ITEM 16H. Mine Safety Disclosure.

Not applicable.

PART III

ITEM 17. Financial Statements.

We have responded to Item 18 in lieu of responding to this item.

ITEM 18. Financial Statements.

Please refer to the financial statements beginning on page F-1. The following financial statements, financial statement schedules and related notes are filed as part of this annual report, together with the report of the independent registered public accounting firm.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Galmed Pharmaceuticals, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Galmed Pharmaceuticals Ltd. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.

Brightman Almagor Zohar & Co.

Certified Public Accountants

Member of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel

March 13, 2019

We have served as the Company's auditor since 2013.

GALMED PHARMACEUTICALS LTD.
Consolidated Balance Sheets

U.S. Dollars in thousands, except share data and per share data

		As of December 31,	
		2018	2017
Assets			
Current assets			
Cash and cash equivalents		$24,159	$13,021
Short-term deposits		6,067	-
Marketable debt securities	3	59,962	5,976
Other accounts receivable	4	218	155
Total current assets		90,406	19,152
Property and equipment, net	5	194	491
Total assets		$90,600	$19,643
Liabilities and stockholders' equity			
Current liabilities			
Trade payables		1,814	2,276
Other accounts payable		892	1,034
Deferred revenue	6	-	538
Total current liabilities		2,706	3,848
Stockholders' equity			
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 21,018,919 shares as of December 31, 2018; 14,435,161 shares as of December 31, 2017	9	58	40
Additional paid-in capital		174,322	92,381
Accumulated other comprehensive loss		(11)	(7)
Accumulated deficit		(86,475)	(76,619)
Total stockholders' equity		87,894	15,795
Total liabilities and stockholders' equity		$90,600	$19,643

Accompanying notes are an integral part of the consolidated financial statements.

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GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Operations

U.S. Dollars in thousands, except share data and per share data

		Year ended December 31,		
		2018	2017	2016
Revenue	6	$2,038	$1,085	$467
Research and development expenses	10	8,313	9,650	14,271
General and administrative expenses	11	4,440	3,799	3,078
Total operating loss		10,715	12,364	16,882
Financial income, net	12	(934)	(65)	(35)
Loss before income taxes		9,781	12,299	16,847
Income taxes	13	75	-	106
Net loss		$9,856	$12,299	$16,953
Basic and diluted net loss per share from continuing operations		$0.54	$0.98	$1.49
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share		18,137,689	12,487,349	11,374,653

Accompanying notes are an integral part of the consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Comprehensive Loss

U.S. Dollars in thousands, except share data and per share data

	Year ended December 31,		
	2018	2017	2016
Net loss	$9,856	$12,299	$16,953
Other comprehensive loss (income):			
Net unrealized loss (gain) on available for sale securities	4	(78)	(121)
Comprehensive loss	$9,860	$12,221	$16,832

Accompanying notes are an integral part of the consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Statements of Changes in Stockholders' Equity

U.S. Dollars in thousands, except share data and per share data

	Ordinary shares					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
Balance - January 1, 2017	12,149,226	$ 34	$ 75,446	$ (85)	$ (64,320)	$ 11,075
Stock-based compensation	–	–	1,394	–	–	1,394
Issuance of Ordinary Shares (*)	1,874,827	5	15,012	–	–	15,017
Issuance of common stock upon stock option exercises	411,108	1	529	–	–	530
Unrealized gain from marketable debt securities	–	–	–	78	–	78
Net loss	–	–	–	–	(12,299)	(12,299)
Balance - December 31, 2017	14,435,161	$ 40	$ 92,381	$ (7)	$ (76,619)	$ 15,795
Stock-based compensation	–	–	1,783	–	–	1,783
Issuance of Ordinary Shares and warrants, net (*)	6,149,260	17	79,132	–	–	79,149
Exercise of options and restricted stock units	434,498	1	1,026	–	–	1,027
Unrealized loss on marketable debt securities	–	–	–	(4)	–	(4)
Net loss	–	–	–	–	(9,856)	(9,856)
Balance - December 31, 2018	21,018,919	$ 58	$ 174,322	$ (11)	$ (86,475)	$ 87,894

*) See also Note 9A.

Accompanying notes are an integral part of the consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Cash Flows

U.S. Dollars in thousands, except share data and per share data

	Year ended December 31,		
	2018	2017	2016
Cash flow from operating activities			
Net loss for the year	$(9,856)	$(12,299)	$(16,953)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	387	239	169
Amortization of discount/premium on marketable debt securities	(144)	21	44
Loss on sale of marketable debt securities	12	143	231
Linked difference of marketable debt securities	-	(167)	–
Stock-based compensation expense	1,783	1,394	1,628
Changes in operating assets and liabilities:			
Increase (decrease) in deferred revenue from collaboration agreement	(538)	(1,085)	1,623
Decrease (increase) in other accounts receivable	(63)	129	95
Increase (decrease) in trade payables	(462)	(846)	863
Increase (decrease) in other accounts payable	(142)	671	81
Increase (decrease) in related party	-	(267)	90
Net cash used in operating activities	(9,023)	(12,067)	(12,129)
Cash flow from investing activities			
Purchase of property and equipment	(90)	(12)	(17)
Proceeds from sale of property and equipment	–	–	13
Investment in securities, available for sale	(92,279)	(3,869)	(7,615)
Proceeds from sale of securities, available for sale	38,421	10,325	13,955
Investment in short-term deposits	(6,067)	–	–
Net cash provided by (used in) investing activities	(60,015)	6,444	6,336
Cash flow from financing activities			
Issuance of ordinary shares and warrants, net of issuance costs (*)	79,149	15,017	4,479
Proceeds from exercise of options	1,027	530	255
Net cash provided by financing activities	80,176	15,547	4,734
Increase (decrease) in cash and cash equivalents	11,138	9,924	(1,059)
Cash and cash equivalents at the beginning of the year	13,021	3,097	4,156
Cash and cash equivalents at the end of the year	$24,159	$13,021	$3,097
Cash received from interest	$865	$202	$382
Cash paid for taxes	$75	$–	$106

*) See also Note 9A.

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

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 1 – General

Galmed Pharmaceuticals Ltd. (the "Company") is a clinical-stage biopharmaceutical company primarily focused on the development of therapeutics for the treatment of liver diseases.

The Company was incorporated in Israel on July 31, 2013 and commenced operations on February 2, 2014.

The Company holds a wholly-owned subsidiary, Galmed International Ltd., which was incorporated in Malta. Galmed International Ltd. previously held a wholly-owned subsidiary, Galmed Medical Research Ltd., which was incorporated in Israel, and had been an inactive company since 2015 and was liquidated on February 2019.

The Company also holds a wholly-owned subsidiary, Galmed Research and Development Ltd., which was incorporated in Israel.

The Company is a clinical-stage biopharmaceutical company with an operating history limited to pre-clinical and clinical drug development and has no approved products. To date, the Company has focused almost exclusively on developing its product candidate, Aramchol. The Company funded its research and development programs and operations to date primarily through proceeds from private placements and public offerings. The Company currently has no products approved for marketing and has not generated any revenue from product sales to date. As of December 31, 2018, the Company had cash and cash equivalents of $24.2 million, short-term deposits of $6.0 million and marketable debt securities of $60.0 million.

The Company has incurred operating losses in each year since inception. The Company's loss attributable to holders of its ordinary shares for the years ended December 31, 2016, 2017, and 2018 was approximately $17.0 million, $12.3 million, and $9.9 million, respectively. As of December 31, 2018, the Company had an accumulated deficit of $86.5 million. Substantially all of its operating losses resulted from costs incurred in connection with the Company's development program and from general and administrative costs associated with its operations.

The Company will need to raise substantial, additional capital to fund its operations and to develop Aramchol for, and beyond its current development stage and any future commercialization, as well as any additional indications.

Based on the Company's current operating plan, the Company's management currently estimates that its cash position will support its current clinical trials and operations as currently conducted for more than 12 months from the date of issuance of these financial statements.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies

A. Basis of presentation

The consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP").

B. Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

C. Financial statement in U.S. dollars

The functional currency of the Company and its subsidiaries is in U.S dollar (the “dollar”), because the dollar is the currency of the primary economic environment in which the Company and its subsidiaries operate, and expect to continue operating in the foreseeable future. Transactions and balances denominated in dollars are presented in their original amounts. Non-dollar denominated transactions and balances have been re-measured to dollars in accordance with the provisions of ASC 830-10, “Foreign Currency Translation.” All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

D. Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: Galmed Research and Development Ltd, Galmed 2000 Inc., Galmed International Ltd., and Galmed Medical Research Ltd. All intercompany balances and transactions have been eliminated upon consolidation.

E. Cash and cash equivalents

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash with maturities of three months or less as of the date acquired.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (Cont.)

F. Marketable debt securities

The Company invests most of its excess cash primarily in debt securities.

Marketable debt securities are considered to be available for sale and are carried at fair value. Unrealized gains and losses net of tax, if any, are reported as a separate component of stockholders' equity. The cost of marketable debt securities classified as available for sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses and declines in value judged to be other than temporary, if any, are also included in other income, net. Interest on securities classified as available for sale is included in interest income. The cost of securities sold is based on the specific identification method.

For all investments in marketable debt securities, the Company assesses whether the impairment is other-than-temporary. If the fair value of a security is less than its amortized cost basis, an impairment is considered other-than-temporary if (i) the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security before recovery of its entire amortized cost basis, or (ii) the Company does not expect to recover the entire amortized cost of the security. If an impairment is considered other-than-temporary based on condition (i), the entire difference between the amortized cost and the fair value of the security is recognized in earnings. If an impairment is considered other-than-temporary based on condition (ii), the amount representing credit losses, defined as the difference between the present value of the cash flows expected to be collected and the amortized cost basis of the security, will be recognized in earnings, and the amount relating to all other factors will be recognized in other comprehensive income. The Company evaluates both qualitative and quantitative factors such as duration and severity of the unrealized losses, credit ratings, default and loss rates of the underlying collateral, structure and credit enhancements to determine if a credit loss may exist.

During the years ended December 31, 2018 and 2017 no other-than-temporarily impaired losses were realized.

G. Concentrations of credit risk

Financial instruments which potentially subject us to credit risk consist primarily of cash, cash equivalents, and marketable securities. We hold these investments in highly-rated financial institutions, and, by policy, limit the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. We have not experienced any credit losses in such accounts and do not believe we are exposed to any significant credit risk on these funds. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

H. Property and equipment

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

	%
Office furniture and equipment	7-16
Computer software, electronic and medical equipment	15–33
Leasehold improvements	10

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (Cont.)

H. Impairment of long-lived assets

The Company's and its subsidiaries' long-lived assets are reviewed for impairment in accordance with ASC 360-10, "Accounting for the Impairment or Disposal of Long-Lived Assets," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds their fair value. During 2018 and 2017, no impairment losses were identified.

I. Severance pay

The Company employees are included under section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. According to Section 14, these employees are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made in their name with such insurance companies. Under the Severance Compensation Act, 1963, payments in accordance with Section 14 release the Company from any future severance payments to those employees. The aforementioned deposits are not recorded as an asset in the Company's balance sheet.

J. Fair value of financial instruments

The estimated fair value of financial instruments was determined by the Company using available market information and valuation methodologies. Considerable judgment is required in estimating fair values. Accordingly, the estimates may not be indicative of the amounts the Company could realize in a current market exchange.

The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments:

The carrying amounts of cash and cash equivalents, short-term bank deposits, other accounts receivables, trade payables and other trade payables approximate their fair value due to the short-term maturity of such instruments.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (Cont.)

J. Fair value of financial instruments (Cont.)

Fair value is an exit price representing the amount that would be received upon selling an asset or that would be paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions used by market participants in pricing an asset or a liability.

A three-tier fair-value hierarchy was established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets
- Level 2 - Other inputs that are directly or indirectly observable in the marketplace; and
- Level 3 - Unobservable inputs that are supported by little or no market activity

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

K. Accounting for stock-based compensation

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

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", which simplifies the accounting for non-employee share-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for share-based payment awards to employees. The amendments expand the scope of the accounting standard for share-based payment awards to include share-based payment awards granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance related to equity-based payments to non-employees. The Company elected to early adopt these amendments on June 1, 2018. The adoption of these amendments did not have a significant impact on our consolidated financial statements and related disclosures.

The Company estimates the fair value of restricted shares based on the market price of the shares at the grant date, and estimates the fair value of stock options granted using a Black-Scholes option-pricing model. The option-pricing model requires a number of assumptions, the most significant of which are the expected stock-price volatility and the expected option term (the time from the grant date until the options are exercised or expire).

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (Cont.)

K. Accounting for stock-based compensation (Cont.)

The Company's calculations of the expected volatility were based upon actual historical stock-price movements over the period, which was equal to the expected option term. The expected option term was calculated for options granted to employees and directors in accordance with ASC-718-10-S99, using the "simplified" method, and grants to non-employees were based on the contractual term. Historically, the Company has not paid dividends, and has no foreseeable plans to do so. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term.

The following assumptions were used for the fiscal year 2018 and 2017 grants: dividend yield of 0.00% for both periods; risk-free interest rate between 1.22% and 1.90%; an expected life between 5 and 6.25 years; and a volatility rate ranging between 70% to 84%.

L. Revenue Recognition

On January 1, 2018, the Company adopted ASC 606 with full retrospective application. The adoption of did not have an effect on either revenue recognized in prior periods, nor to accumulated deficit as of January 1, 2017.

The new revenue standard amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The new revenue standard provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of the new revenue standard, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligations are satisfied.

The Company only applies the five-step model to contracts when collectability of the consideration to which the Company is entitled in exchange for the goods or services transferred to the customer is determined to be probable. At contract inception, once the contract is determined to be within the scope of the new revenue standard, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. The Company then allocates the transaction price (the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied. The Company's estimate of the transaction price for each contract includes all variable consideration to which we expect to be entitled.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 - Significant Accounting Policies (Cont.)

M. Research and development expenses

Research and development expenses are charged to the statement of operations as incurred.

N. Income taxes

The Company accounts for income taxes utilizing the asset and liability method in accordance with ASC 740, "Income Taxes." Current tax liabilities are recognized for the estimated taxes payable on tax returns for the current year. Deferred tax liabilities or assets are recognized for the estimated future tax effects attributable to temporary differences between the income-tax bases of assets and liabilities and their reported amounts in the financial statements and for tax loss carry forwards. Measurement of current and deferred tax liabilities and assets is based on provisions of enacted tax laws, and deferred tax assets are reduced, if necessary, by the amount of tax benefits, the realization of which is not considered more likely than not based on available evidence.

ASC 740-10 requires a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 - Significant Accounting Policies (Cont.)

O. Basic and diluted net loss per share

Basic net loss per share is computed based on the weighted-average number of shares outstanding during each year. Diluted net loss per share is computed based on the weighted-average number of shares outstanding during each year, plus the dilutive potential of the ordinary shares considered outstanding during the year, in accordance with ASC 260-10, “Earnings Per Share.”

All outstanding stock options and warrants were excluded from the calculation of the diluted loss per share for the years ended December 31, 2018, 2017 and 2016, because all such securities have an anti-dilutive effect.

P. Segment Reporting

The chief operating decision maker for the Company is the Chief Executive Officer. The Chief Executive Officer reviews financial information presented on a consolidated basis for purposes of allocating resources and evaluating financial performance. Accordingly, management has determined that the Company operates in one reportable segment.

Q. Comprehensive Loss

The purpose of reporting comprehensive income is to report a measure of all changes in equity of an entity that result from recognized transactions and other economic events of the period resulting from transactions from non-owner sources.

R. Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards

that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 2 - Significant Accounting Policies (Cont.)

R. Recently issued accounting pronouncements (Cont.)

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (Topic 842) ("ASU 2016-02"), which amends, among other things, the existing guidance by requiring lessees to recognize lease assets (right-to-use) and liabilities (for reasonably certain lease payments) arising from operating leases on the balance sheet. For leases with a term of twelve months or less, ASU 2016-02 permits an entity to make an accounting policy election to recognize such leases as lease expense, generally on a straight-line basis over the lease term. This ASU is effective for the Company in its first quarter of fiscal year 2019. The Company is in the process of implementing changes to its systems and processes in conjunction with its review of lease agreements. The Company intends to adopt ASU 2016-02 effective January 1, 2019 and expects to elect certain available transitional practical expedients.

The Company expects that this standard will have an effect on its financial statements. While the Company continues to assess all of the effects of adoption, it currently believes the most significant effects relate to the recognition of new right-of-use ("ROU") assets and lease liabilities on its balance sheet for real estate operating leases and car leases. Upon adoption, the Company currently expects to recognize additional operating liabilities of approximately $0.8 million, with corresponding ROU assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

In June 2016, FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses – Measurement of Credit Losses on Financial Instruments", which introduces a model based on expected losses to estimate credit losses for most financial assets and certain other instruments. In addition, for available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. The ASU is effective for the Company in the first quarter of 2020, with early adoption permitted. The Company is currently evaluating the effect the adoption of this ASU will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements", which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements, and is effective for the Company beginning on January 1, 2020. The Company does not expect that this standard will have a material effect on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18 "Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606". The standard provides guidance on how to assess whether certain transactions between participants in collaborative arrangements should be accounted for within the board’s revenue recognition standard. The amendments in the new standard take effect for the Company on January 1, 2020. Early adoption is permitted. The Company is assessing the impact, if any, the standard has on its consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 3 – Marketable debt securities

The following table summarizes the Company's marketable debt securities as of December 31, 2018 and 2017.

	As of December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	**Estimated Fair Value**
	(in thousands)			
Corporate debt securities	$59,973	$ 56	$ (67)	$ 59,962
Total short-term investments	$59,973	$ 56	$ (67)	$ 59,962

	As of December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	**Estimated Fair Value**
	(in thousands)			
Corporate debt securities	$5,983	$ 7	$ (14)	$ 5,976
Total short-term investments	$5,983	$ 7	$ (14)	$ 5,976

The Company's financial assets are measured at fair value on a recurring basis by level within the fair value hierarchy. All of the Company's marketable securities are classified as Level 1. Other than the marketable debt securities, the Company doesn't have any other financial assets or financial liabilities marked to market at fair value.

The contractual maturity of the aforementioned marketable securities varies between less than one year to two years.

The Company reviews the individual securities in its portfolio to determine whether a decline in a security's fair value below the amortized cost basis is other-than-temporary. The Company determined that as of December 31, 2018 and 2017 there were no investments in its portfolio that were other-than-temporarily impaired.

*) See also note 8.3

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GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 4 – Other Accounts Receivable

	As of December 31,	
	2018	2017
	(in thousands)	
Government institutions	$ 51	$ 55
Prepaid expenses	167	100
	$ 218	$ 155

Note 5 – Property and equipment, net

	As of December 31,	
	2018	2017
	(in thousands)	
Medical equipment	$ 737	$ 737
Office furniture and equipment	55	35
Computer software and electronic equipment	78	69
Leasehold improvements	196	133
	1,066	974
Less - Accumulated depreciation	872	483
Net book value	$ 194	$ 491

Note 6 – Revenue

Samil Agreement

On July 28, 2016, the Company entered into a license agreement ("Samil Agreement") with Samil Pharm. Co., Ltd. (the “Samil”), for an exclusive, royalty-bearing license for the commercialization of Aramchol (with an option to manufacture) for the treatment of fatty liver indications including NASH in the Republic of Korea. Additionally, following the ARREST Study, Samil has an option to extend the License to Vietnam, which, if exercised, would increase the clinical- and regulatory-based milestone payments.

Under the terms of the Samil Agreement, the Company received an up-front payment of approximately $2.1 million. Samil has also agreed to pay additional clinical and regulatory-based milestone payments, which may aggregate up to $6.0 million, as well as tiered, double-digit royalties payable on sales (under certain limitations). In September, 2018 the Company received a milestone payment of $1.5 million from Samil in connection with the completion of its ARREST study.

In accordance with ASC 606 the Company determined that the Agreement included a combined performance obligation representing the delivery of the exclusive license and completion of the ARREST study.

The Company determined that the transaction price at contract inception was $2.1 million consisting of the upfront, non-refundable payment. None of the clinical or regulatory milestones were included in the transaction price upon inception, as all milestone amounts were fully constrained. Management assessed that the likelihood of occurrence of the other performance obligations in the Agreement was remote upon contract inception. As such, the stand-alone value of such performance obligations was deemed de minimis and none of the transaction price was allocated to those obligations. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, and therefore have also been excluded from the transaction price.

During 2018, when the Company determined that the achievement of its first milestone was probable, it included the variable consideration of $1.5 million as a part of the transaction price allocated to the combined performance obligation including the delivery of the license and completion of the ARREST study. The Company will re-evaluate the transaction price in each reporting period when events whose outcomes are resolved or other changes in circumstances occur that would indicate it is appropriate to recognize variable consideration as revenue.

Revenue allocated to the combined performance obligation of the license and associated ARREST study was recognized ratably, based on the input method, from contract inception through conclusion of the ARREST study in June 2018.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 7 – Related Parties

A. Balances

As of December 31, 2018, and 2017, the Company had an accrual in the amount of approximately $0.8 million and $0.9 million, respectively, pursuant to an employment agreement with its officers and directors' fee.

B. Transactions

1. During 2018, 2017 and 2016, the Company recorded salary expenses, stock based compensation expenses and directors' fee to its related parties in the amount of $3.7 million, $3.4 million and $2.5 million respectively.

2. On April 5, 2018, the Company sold to Biotechnology Value Fund, L.P. and certain of its affiliates in a registered direct offering 1,000,000 ordinary shares and warrants to purchase 1,000,000 ordinary shares, for a purchase price of $6.00 per share and related warrant. Each warrant may be exercised at any time and from time to time through and including the one-year anniversary of the initial exercise date at an exercise price of $15.00 per share, subject to certain adjustments. The net proceeds to the Company, after deducting offering expenses, were $5.96 million.

2. In July 2018, the Company granted options to purchase 630,000 ordinary shares of the Company to its directors. The options are exercisable at $11.56 per share, have a 10 year term and vest over a period of one year. The aggregate grant date fair value of such options is approximately $5.6 million.

Note 8 – Commitments and Contingencies

A. Contingencies

1. In March 2015, the Company entered into a lease agreement for its corporate headquarters. The lease has a term of four years with an option to extend the lease agreement for an additional two years. In February 2017 and August

2018, the Company leased additional spaces adjacent to the current premises. In addition, in August 2018, the Company was granted two additional options to extend the lease for one year each. In November 2018, the Company exercised the original option to extend the lease for an additional two years. To secure lease payments, the Company provided a bank guarantee of $46 thousand.

2. As of December 31, 2018, the Company recorded a pledge on its marketable debt securities in favor of its bank in the amount of approximately $113 thousand to secure the Company's commitments to the bank.

B. Commitments

The following table summarizes the Company’s significant contractual obligations at December 31, 2018:

	Total	Less than 1 year	1-3 years
	(in thousands)		
Facility leases	$676	$ 150	$ 526
Total	$676	$ 150	$ 526

The Company enters into contracts in the ordinary course of business with Contract Research Organizations for clinical trials and clinical supply manufacturing and with vendors for non-clinical research studies and other services and products for operating purposes, which generally provide for termination upon 30 days notice or less, and therefore are cancelable contracts and not included in the table above. The Company has included as purchase obligations our commitments under agreements to the extent they are quantifiable and are not cancelable.

Other than as described above, the Company 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, 2018.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 9– Shareholders' Equity

A. Ordinary shares

1. Ordinary shares confer upon the holders the right to receive notice to participate and vote in general meetings of the Company and the right to receive dividends, if declared.

2. In August 2017, the Company sold 332,038 ordinary shares at a price of $7.10 in a registered direct offering, and in a concurrent private placement to two of the Company's directors sold 49,295 ordinary shares at the same price. The aggregate net proceeds received from the offering was approximately $2.7 million.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 9 – Shareholders' Equity (Cont.)

A. Ordinary shares (Cont.)

3. On May 31, 2016, the Company entered into a Controlled Equity Offering Sales Agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald & Co., as the Company's sales agent ("Cantor Fitzgerald"), to issue and sell, from time to time through Cantor Fitzgerald, ordinary shares having an aggregate offering price of up to $16 million. Under the Cantor Sales Agreement, the Company was entitled to sell ordinary shares by any method permitted by law and deemed to be an "at-the-market" offering, as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company was not obligated to make any sales under the Cantor Sales Agreement. The Cantor Sales Agreement was terminated during December, 2017. As of the termination of the agreement, the Company sold 1,712,369 ordinary shares under the Cantor Sales Agreement for total net proceeds of approximately $11.0 million

4. On December 22, 2017, the Company entered into an At-the-Market Equity Offering Sales Agreement (the "Stifel Sales Agreement") with Stifel, Nicolaus & Company, Incorporated, as the Company's sales agent ("Stifel"). Pursuant to the prospectus relating to the Company's shelf registration statement on Form F-3 filed with the SEC on March 26, 2018 (File No. 333-223923) the Company may offer and sell, from time to time through Stifel, its ordinary shares having an aggregate offering price of up to $35 million. As of December 31, 2018, the Company sold 863,545 ordinary shares under the Stifel Sales Agreement for total net proceeds of approximately $8.6 million.

5. On April 5, 2018, the Company sold to Biotechnology Value Fund, L.P. and certain of its affiliates in a registered direct offering 1,000,000 ordinary shares and warrants to purchase 1,000,000 ordinary shares, for a purchase price of $6.00 per share and related warrant. Each warrant may be exercised at any time and from time to time through and including the one-year anniversary of the initial exercise date at an exercise price of $15.00 per share, subject to certain adjustments. The net proceeds to the Company, after deducting offering expenses, were $5.96 million.

6. On June 22, 2018, the Company completed an underwritten public offering of 5,000,000 ordinary shares, at a public offering price of $15.00 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses, were $70.3 million.

B. Stock-based compensation

1. The Company has an equity-based incentive plan, the 2013 Incentive Share Option Plan (the "2013 Plan"). As of December 31, 2018, a total of 784,087 shares were reserved for issuance under the 2013 Plan. The 2013 Plan, which

was adopted by the Board on September 2, 2013, and approved by the Company’s shareholders on December 30, 2013 (as was amended by the Board and the Company’s shareholders on March 30, 2015, May 11, 2015, and August 30, 2018 respectively), provides for the grant of options to purchase the ordinary shares and the issuance of restricted stock units (“RSUs”) to the Company's officers, directors, employees, service providers and consultants. The 2013 Plan provides for such equity-based compensation under various and different tax regimes.

2. A summary of the status of the Company’s option plans as of December 31, 2018 and 2017 and changes during the years then ended are presented below:

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 9 – Shareholders' Equity (Cont.)

B. Stock-based compensation

	2018		2017	
	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price
Options outstanding at beginning of year	2,106,930	$ 4.01	2,421,106	$ 3.80
Granted	763,500	$ 10.75	226,000	$ 4.86
Forfeited	(101,250)	$ 10.70	(160,000)	$ 6.95
Exercised	(420,126)	$ 2.45	(380,176)	$ 1.39
Outstanding at end of year	2,349,054	$ 5.92	2,106,930	$ 4.01
Options exercisable at year end	1,356,377	$ 3.51	1,406,074	$ 2.69

As of December 31, 2018, and 2017, the weighted-average remaining contractual term of the outstanding and exercisable options, excluding the 38,637 options granted in 2002 that have no expiration date, is 7.29 and 6.95 years, respectively.

The weighted average grant date fair value of the options granted during the years ended December 31, 2018, 2017 and 2016 is $8.19, $4.86, and $3.76 respectively.

As of December 31, 2018, a total of the 1,550,612 outstanding and exercisable options are "in the money" with aggregate intrinsic value of $5.8 million; while as of December 31, 2017 a total of 2,096,714 outstanding and exercisable options were "in the money" with aggregate intrinsic value of $11.4 million.

The unrecognized compensation expense calculated under the fair-value method for stock options expected to vest as of December 31, 2018 and 2017 is approximately $6.5 million and $3.1 million, respectively, and is expected to be recognized over a weighted-average period of 3.1 years and 1.9 years, respectively.

For the years ended 2018, 2017 and 2016, the Company recorded a total of $1.8 million, $1.4 million, and $1.6 million of stock-based compensation expenses, in connection with the above-mentioned option.

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Notes to Consolidated Financial Statements

Note 9 – Shareholders' Equity (Cont.)

B. Stock-based compensation (Cont.)

During 2016, the Company issued a total of 78,750 RSUs. Upon vesting, each RSU will settle by the issuance of one ordinary share. The RSUs vest over four years. As of December 31, 2018, a total of 41,462 ordinary shares were issued upon vesting of 45,309 RSUs and a total of 13,869 RSUs were outstanding, while as of December 31, 2017, a total of 30,932 ordinary shares were issued upon vesting of 30,932 RSUs and a total of 32,348 RSUs were outstanding.

3. For the years 2018, 2017 and 2016, with respect to the above-mentioned RSUs, the Company recorded stock-based compensation expenses in the amount of $94 thousand, $105 thousand and $124 thousand, respectively. All of the above-mentioned stock-based compensation expenses are recorded under the G&A expenses.

The unrecognized compensation expense calculated under the fair-value method for stock options expected to vest as of December 31, 2018 and 2017 is approximately $99 thousand and $193 thousand, respectively, and is expected to be recognized over a weighted-average period of one year and two years, respectively.

Note 10 – Research and Development Expenses

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
Chemistry and formulation studies	$968	$820	$1,802
Salaries	1,617	1,090	1,004
Stock-based compensation	582	585	757
Research and preclinical studies	963	684	924
Clinical studies	3,575	5,871	9,263
Regulatory and other expenses	608	600	521
	$8,313	$9,650	$14,271

Note 11 – General and Administrative Expenses

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
Stock-based compensation	$1,201	$809	$871
Professional fees	896	622	683
Salaries and benefits	1,346	1,441	849
Rent and office-maintenance fees	308	269	303
Investor relations and business development expenses	464	460	248
Insurance and other	225	198	124
	$4,440	$3,799	$3,078

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Notes to Consolidated Financial Statements

Note 12 – Financial income, net

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
Other expenses	$ 42	$ 49	$ 67
Interest income	(959)	(202)	(382)
Loss (gain) from sale of marketable debt securities	(12)	182	305
Foreign currency gains	(5)	(94)	(25)
	$ (934)	$ (65)	$ (35)

Note 13 – Income Taxes

A. General

The Company is assessed for tax purposes on an unconsolidated basis. Each of the Company's subsidiaries is subject to the tax rules prevailing in its country of incorporation.

B. Corporate Taxation

Israeli subsidiary:

In January 2016, the Israeli corporate income tax law was amended and reduced as of January 1, 2016 to 25% (from 26.5%). In December 2016, the Israeli corporate income tax law was further amended and reduced as of January 1, 2017 to 24% and as of January 1, 2018 to 23%.

On February 7, 2018, the Israeli Tax Authority issued a ruling granting the Company's Israeli subsidiary "Preferred Technological Enterprise" status as defined under the Encouragement of Capital Investment Law -1959 (the "Approval"). The grant of the status means that the Company's Israeli subsidiary will be subject to a reduced Israeli corporate tax rate that will range between 6%-12% on any future taxable "technological income" which includes sales,

licenses and royalties from its IP protected products. The tax ruling applies for five years until 2022 and may be extended for further periods subject to meeting certain requirements.

Maltese subsidiary:

Taxable income of Maltese companies is subject to tax at the rate of 35% in 2018 and 2017 (“Regular Tax Rate”).

C. Net Operating Loss Carry forward

As of December 31, 2018, the Company had approximately $63.9 million net-operating-loss carry forwards, consisting of approximately $12.0 million of Maltese net-operating-loss carry forwards and approximately 51.9 million Israeli net-operating-loss carry forward. Additionally, the Company had approximately $1.2 million of capital loss carry forward from the sale of marketable debt securities. The Maltese and the Israeli loss carry forwards have no expiration date.

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Notes to Consolidated Financial Statements

Note 13 – Income Taxes (Cont.)

D. Deferred income taxes

Deferred-tax assets for carry forward losses in Malta and Israel are calculated using the applicable tax rate at the time of expected realization of the carry forward losses. The Company has provided full valuation allowances in respect of deferred-tax assets. Management currently believes that it is more likely than not that those deferred taxes will not be realized in the foreseeable future.

Significant components of the Company's and its subsidiaries' assets are as follows

	As of December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets		
Israeli subsidiary net-operating-loss carry forward	$ 6,230	$ 4,868
Maltese subsidiary net-operating-loss carry forward	4,611	4,611
Israeli subsidiary capital-loss carry forward	294	142
Other reserves and allowances	16	12
Total deferred-tax assets	11,151	9,633
Valuation allowance	(11,151)	(9,633)
Net deferred-tax assets	$ –	$ –

E. Tax assessments

The Israeli subsidiaries received final tax assessments through the year ended December 31, 2013.

F. Effective tax expense

A reconciliation of the Company's effective tax expense to the Company's theoretical statutory tax benefit is as follows:

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
Loss before taxes on income, as reported in the consolidated statements of operations	$9,781	$12,299	$16,847
Statutory tax rate	12 %	24 %	25 %
Theoretical tax benefit	1,174	2,952	4,212
Losses and other items for which a valuation allowance was provided or benefit from loss carry forwards	(1,174)	(2,952)	(4,212)
Tax withheld from upfront payment from Samil	75	-	105
Others	-	-	1
Actual tax expense	$75	$-	$106

ITEM 19. Exhibits.

Exhibit No.	Description
1.1	Form of Amended and Restated Articles of Association of Galmed Pharmaceuticals Ltd. (English Translation) (1)
4.1	Form of Indemnification Agreement (1)
4.2	Galmed Pharmaceuticals Ltd. 2013 Incentive Share Option Plan (4)
4.3	Registration and Information Rights Agreement, dated December 2013, by and among Galmed Pharmaceuticals Ltd., Shirat HaChaim Ltd., David & Debora Goldfarb, Medgal S.A. and G. Yarom Medical Research Ltd. (2)
4.4	Personal Employment Agreement, dated December 23, 2013, by and between Galmed Medical Research Ltd. and Allen Baharaff (2)
4.5	Amendment No.1 to Employment Agreement by and between Galmed Research and Development Ltd. and Allen Baharaff (11)
4.6	Compensation Policy of Galmed Pharmaceuticals Ltd.(5)
4.7	Lease, dated March 22, 2015, between Galmed Research and Development Ltd. and Mintz K. Construction Company Ltd.(8)
4.8	Addendum to Lease, dated February 27, 2017, between Galmed Research and Development Ltd. and Mintz K. Construction Company Ltd.(8)
4.9	Addendum to Lease, dated August 8, 2018, between Galmed Research and Development Ltd. and Mintz K. Construction Company Ltd.**
4.10	Form of Registered Direct Securities Purchase Agreement (9)
4.11	Form of Private Placement Securities Purchase Agreement (9)
4.12	At-the-Market Equity Offering Sales Agreement, dated December 22, 2017, by and between Galmed Pharmaceuticals Ltd. and Stifel, Nicolaus & Company, Incorporated (10)
4.13	Form of Securities Purchase Agreement dated as of April 2, 2018 between Galmed Pharmaceuticals Ltd. and the purchasers named therein (12)
4.14	Form of Warrant of Galmed Pharmaceuticals Ltd. issued on April 5, 2018 (13)

4.15	Underwriting Agreement between Galmed Pharmaceuticals Ltd. and Stifel, Nicolaus & Company, Incorporated, as representative of the several underwriters, dated June 19, 2018 (14)
8.1	List of subsidiaries of Galmed Pharmaceuticals Ltd.**
11.1	Code of Business Conduct and Ethics of Galmed Pharmaceuticals Ltd.(7)
12.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
12.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
13.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) and 15d-14(b) and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

15.1	Consent of Brightman Almagor Zohar & Co. (a Member of Deloitte Touche Tohmatsu Limited)**
101	The following financial information from Galmed Pharmaceuticals Ltd.'s Annual Report on Form 20-F for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Shareholders' Equity (iii) the Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements**

(1)	Incorporated herein by reference to Amendment No. 1 to the Registration Statement on Form F-1, filed with the SEC on February 28, 2014.
(2)	Incorporated herein by reference to the Registration Statement on Form F-1, filed with the SEC on February 6, 2014.
(3)	Incorporated herein by reference to the Company's Report on Form 6-K filed with the SEC on June 1, 2016.
(4)	Incorporated herein by reference to Exhibit A to the Company's Report on Form 6-K filed with the SEC on April 2, 2015.
(5)	Incorporated herein by reference to Exhibit A to the Company's Report on Form 6-K filed with the SEC on April 27, 2017.
(6)	Incorporated herein by reference to the Company's Annual Report on Form 20-F filed with the SEC on March 31, 2015.
(7)	Incorporated herein by reference to the Company's Annual Report on Form 20-F filed with the SEC on March 22, 2016.
(8)	Incorporated herein by reference to the Company's Annual Report on Form 20-F filed with the SEC on March 23, 2017.
(9)	Incorporated herein by reference to Exhibit 1.1 to the Company's Report on Form 6-K filed with the SEC on August 7, 2017.
(10)	Incorporated herein by reference to Exhibit 1.1 to the Company's Report on Form 6-K filed with the SEC on December 22, 2017.
(11)	Incorporated herein by reference to the Company's Annual Report on Form 20-F filed with the SEC on March 13, 2018.
(12)	Incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 6-K filed with the SEC on April 4, 2018.
(13)	Incorporated herein by reference to Exhibit 4.1 to the Company's Report on Form 6-K filed with the SEC on April 4, 2018.
(14)	Incorporated herein by reference to Exhibit 1.1 to the Company's Report on Form 6-K filed with the SEC on June 21, 2018.

* Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment under Rule 24b-2 of the Exchange Act.

** Filed herewith.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

GALMED PHARMACEUTICALS LTD.

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

Date: March 13, 2019