Foamix Pharmaceuticals Ltd.
Form 20-F
February 21, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

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

For the fiscal year ended December 31, 2016

Commission file number: 001-36621

Foamix Pharmaceuticals Ltd.
(Exact name of Registrant as specified in its charter)

State of Israel
(Jurisdiction of incorporation or organization)

2 Holzman Street, Weizmann Science Park
Rehovot 7670402, Israel
Tel: +972-8-9316233
(Address of principal executive offices)

Mr. Ilan Hadar, Chief Financial Officer
2 Holzman Street, Weizmann Science Park
Rehovot 7670402, Israel
Tel: +972-8-931-6233
(Name, Telephone 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 of NIS 0.16	NASDAQ Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

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.

37,167,791 Ordinary Shares, par value NIS 0.16 per share.

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

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

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 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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer

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

U.S. GAAP

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

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INTRODUCTION

Unless otherwise indicated, all references to the "Company," "we," "us," "our" and "Foamix" refer to Foamix Pharmaceuticals Ltd. and its subsidiary, Foamix Pharmaceuticals Inc., a Delaware corporation. References to "U.S. dollars" and "$" are to currency of the United States of America, and references to "NIS" are to new Israeli shekels. References to "Ordinary Shares" are to our ordinary shares, par value of NIS 0.16 per share.

We do not endorse or adopt any third-party research or forecast firms' statements or reports referred to in this annual report and assume no responsibility for the contents or opinions represented in such statements or reports, nor for the updating of any information contained therein.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains express or implied "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws.

These forward-looking statements include, but are not limited to, statements regarding the following matters:

- U.S. Food and Drug Administration, or FDA, approval of, or other regulatory action in the U.S. and elsewhere with respect to, our product candidates;
- the commercial launch and current products or future candidates;
- our ability to achieve favorable pricing for our product candidates;
- our expectations regarding the commercial supply of our product candidates;
- third-party payor reimbursement for our product candidates;
- our estimates regarding anticipated expenses, capital requirements and needs for additional financing;
- the patient market size of any diseases and market adoption of our products by physicians and patients;
- the timing, cost or other aspects of the commercial launch of our product candidates;
- completion and receiving favorable results of clinical trials for our product candidates;
- application for and issuance of patents to us by the United States Patent and Trademark Office, or U.S. PTO, and other governmental patent agencies;
- development and approval of the use of our product candidates for additional indications; and
- our expectations regarding licensing, business transactions and strategic operations.

In some cases, forward-looking statements are identified by terminology such as "may," "will," "could," "should," "expects," "plans," "anticipates," "believes," "intends," "estimates," "predicts," "potential," or "continue" or the negative of these terms or other comparable terminology. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or performance to differ materially from those projected. 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. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not be different, and historic results referred to in this press release may be interpreted differently in light of additional research and clinical and preclinical trials results. The forward-looking statements contained in this annual report are subject to risks and uncertainties, including those discussed under "Item 3.D. Risk Factors" and in our other filings with the Securities and Exchange Commission, or the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to (and expressly disclaim any such obligation to) update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this annual report.

PART ONE

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. Selected financial data

Our historical consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States and are presented in U.S. dollars. The selected historical consolidated financial information as of December 31, 2016 and 2015 and for the years ended December 31, 2016, 2015 and 2014 have been derived from, and should be read in conjunction with, the consolidated financial statements of Foamix Pharmaceuticals Ltd. and notes thereto appearing elsewhere in this annual report. The selected financial data as of December 31, 2014, 2013 and 2012 and for the year ended 2013 and 2012, have been derived from audited consolidated financial statements of Foamix Pharmaceuticals Ltd. not included in this annual report.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this annual report, and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion under "Item 5. Operating and Financial Review and Prospects" - included elsewhere in this annual report.

Consolidated Statement of Operations Data – Year Ended December 31

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

	Year ended December 31,				
	2016	2015	2014	2013	2012
Statements of operations data:					
Revenues	$5,527	$849	$5,414	$1,404	$1,086
Cost of revenues[(1)]	59	70	527	453	491
Gross profit	5,468	779	4,887	951	595
Operating expenses:					
Research and development[(1)]	25,897	10,680	3,557	1,086	1,202
Selling, general and administrative[(1)]	9,221	7,029	2,964	1,221	953
Total operating expenses	35,118	17,709	6,521	2,307	2,155
Operating loss	29,650	16,930	1,634	1,356	1,560
Net Loss	$29,336	$16,517	$11,484	$2,431	$2,169
Loss per share basic and diluted	0.91	0.58	0.79	0.22	0.20

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(1) Includes share-based compensation expenses as follows:

	Year ended December 31,				
	2016	2015	2014	2013	2012
Cost of revenues	$3	$2	$15	$16	$23

Research and development	1,135	588	80	59	83
Selling, general and administrative	1,774	1,187	102	430	249
Total share-based compensation	$2,912	$1,777	$197	$505	$355

Consolidated Balance Sheet Data – Year Ended December 31

(in thousands of U.S. dollars)

	As of December 31,				
	2016	2015	2014	2013	2012
Balance sheet data:					
Cash, cash equivalents, restricted cash, bank deposits, marketable securities and restricted marketable securities	$130,988	$103,779	$49,966	$2,308	$950
Working capital[(1)]	111,730	53,091	48,757	1,144	836
Total assets	135,635	105,245	51,277	3,086	1,389
Total long-term liabilities	379	385	381	4,917	3,967
Total shareholders' equity (capital deficiency)	129,985	100,802	48,762	(3,582)	(2,941)
Capital stock	$1,561	$1,284	$954	$471	$459
Number of ordinary shares	37,167,791	30,639,134	22,443,934	11,408,490	11,151,719

(1) Working capital is defined as total current assets minus total current liabilities.

3.B. Capitalization and indebtedness

Not applicable.

3.C. Reasons for the offer and use of proceeds

Not applicable.

3.D. Risk factors

In conducting our business, we face many risks that may interfere with our business objectives. Some of these risks could materially and adversely affect our business, financial condition and results of operations. In particular, we are subject to various risks resulting from changing economic, political, industry, business and financial conditions. The risks and uncertainties described below are not the only ones we face.

You should carefully consider the following factors and other information in this annual report. If any of the negative events referred to below occur, our business, financial condition and results of operations could suffer. In any such case, the trading price of our ordinary shares could decline.

Risks Related to Our Business and Industry

We are largely dependent on the success of our lead product candidates, FMX101 and FMX103 for the treatment of acne and rosacea.

We have invested a majority of our efforts and financial resources in the research and development of FMX101 for the treatment of moderate-to-severe acne and FMX103 for the treatment of moderate-to-severe papulo-pustular rosacea, which have both completed Phase II clinical trials. We continue to dedicate our resources toward (i) completion of our Phase III clinical trials for FMX101 during the first half of 2017 and filing a new drug application, or NDA, with the FDA during 2018; (ii) commencing Phase III clinical trials for FMX103 during 2017; and (iii) advancing our other pipeline candidates. The success of our business depends largely on our ability to fund, execute and complete the development of, obtain regulatory approval for and successfully commercialize FMX101 and FMX103 in a timely manner. If we fail to do so, we may not be able to obtain adequate funding to continue to operate our business.

We have not completed Phase III clinical trials for any of our product candidates, nor have we applied for regulatory approvals to market any of our product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize our product candidates.

The process of developing, obtaining regulatory approval for and commercializing our product candidates is long, complex, costly and uncertain, and delays or failure can occur at any stage.

The research, testing, manufacturing, labeling, marketing, sale and distribution of drugs are subject to extensive and rigorous regulation by the FDA, and foreign regulatory agencies. These regulations are agency-specific and differ by jurisdiction. We are not permitted to market any of our product candidates in the U.S. until we receive approval of a NDA, from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory agencies in such countries. To gain approval of an NDA or other equivalent regulatory approval, we must provide the FDA or relevant foreign regulatory authority with clinical data that demonstrates the continued safety, purity and potency of the product for the intended indication.

Before we can submit an NDA to the FDA or similar applications to foreign regulatory authorities, for FMX101 or FMX103, our leading product candidates, we must complete Phase III clinical trials for them. These clinical trials are substantially broader than our Phase II clinical trials and have required (or will require) us to enlist a considerably

larger number of patients in multiple clinics and medical centers. We have not received formal regulatory clearance to file an NDA with the FDA or comparable applications to foreign regulatory authorities. Our other product candidates are at similar or earlier stages of development and therefore subject to similar or even greater uncertainty and risk than FMX101 and FMX103.

Phase III clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA or foreign regulatory authorities even if we believe those clinical trials to be successful. The FDA or applicable foreign regulatory agencies may suspend one or all of our clinical trials or require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or similar foreign regulatory application we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed, or may require us to expend more resources than we have available. It is also possible that additional studies we conduct may not be considered sufficient by the FDA or applicable foreign regulatory agencies to provide regulatory approval.

If any of these outcomes occur, we would not receive approval for FMX101, FMX103 or our other product candidates and may be forced to cease operations.

We have conducted only one Phase II clinical trial relating to each of FMX101, FMX102, FMX103 and FDX104, in each case outside the U.S., the results of which may not be predictive of future trial results.

Positive results in preclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase III, after promising results in preclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse events.

To date, we have conducted only one Phase II clinical trial for each of FMX101, FMX102, FMX103 and FDX104 which met their respective primary efficacy and secondary endpoints. Our Phase III clinical trials for our lead product candidates may not be successful, and even if they are, the FDA may not approve our NDA for such product candidates, should we be in position to file one, and may not agree that the benefits of such product candidates outweigh its risks, or may raise new concerns regarding our clinical trial designs.

If the FDA does not conclude that FMX101 or FMX103 satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or Section 505(b)(2), or if the requirements for this product candidate under Section 505(b)(2) are not as we expect, the approval pathway for this product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We expect to complete our pivotal Phase III trials for FMX101 and commence pivotal Phase III trials for FMX103 under the FDA's 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development program for FMX101 and FMX103 by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely increase significantly. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, our product candidates may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of certain products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's

interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway for FMX101 and FMX103, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if these product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Our Phase II clinical trials were not conducted head-to-head with the current standard of care drugs, the comparison of our results to those of existing drugs, and the conclusions we have drawn from such comparisons, may be inaccurate, and the FDA may require our Phase III trials to be controlled against such drugs.

Our Phase II clinical trials for FMX101, FMX102, FMX103 and FDX104 were not conducted in head-to-head comparison with the drugs considered the current standard of care for the relevant indications, namely Solodyn for moderate-to-severe acne, Bactroban for impetigo, topical antimicrobials (such as such as Metrogel, generic metronidazole and Finacea) for rosacea and oral doxycycline for chemotherapy induced rash. This means that none of the patient groups participating in these trials were treated with the standard of care drugs alongside the groups treated with our product candidates. Instead, we have compared the results of our clinical trials with historical data from prior clinical trials conducted for the standard of care drugs, as presented in their respective product labels.

Direct comparison generally provides more reliable information about how two or more drugs compare, and reliance on indirect comparison for evaluating their relative efficacy or other qualities is problematic due to lack of objective or validated methods to assess trial similarity. For example, the various trials were likely conducted in different countries with different demographic features and in patients with different baseline conditions and different hygiene standards, among other relevant asymmetries. Therefore, the conclusions we have drawn from comparing the results of our trials with those published in the product labels for these current standards of care drugs, including conclusions regarding the relative efficacy and expediency of FMX101, FMX102, FMX103 and FDX104, may be distorted by the inaccurate methodology of the comparison.

The FDA may require the Phase III clinical trials of our product candidates to be controlled against the drugs that are currently considered the standards of care for the treatment of the relevant indications, instead of being controlled against a placebo or against a different dosage of our minocycline foam, as was the case in our Phase II clinical trials. Furthermore, even if the FDA does not impose such a requirement in connection with our Phase III clinical trials, the FDA generally requires adequate, well-controlled head-to-head clinical trials to support comparative claims regarding marketed products. As a result, we may decide to conduct comparative studies of FMX101, FMX103 or any of our other product candidates that are commercialized to support comparative claims used in the marketing of those product candidates. Significant additional time and expense will be required to design and conduct any head-to-head trials. For example, in the case of FMX101 for moderate-to-severe acne, the standard of care is an oral drug, Solodyn, whereas FMX101 is a topical drug. To conduct a double blind study comparing the two treatments, all patients would need to receive both modalities, with either the oral or topical treatment consisting of a placebo, increasing the complexity and cost. If we are unable to conduct head-to-head trials for one or more of our product candidates, even if such product candidates are approved for marketing in the U.S., we will not be able to make claims comparing such product candidates to the current standards of care or other competitor products which may negatively impact sales of these products.

Our ability to finance our operations and generate revenues depends on the clinical and commercial success of FMX101, FMX103 and our other product candidates and failure to achieve such success will negatively impact our business.

Our near-term prospects, including our ability to finance our operations and generate revenues, depend on the successful development, regulatory approval and commercialization of FMX101 and FMX103, as well as our other product candidates. The clinical and commercial success of FMX101, FMX103 and our other product candidates depends on a number of factors, many of which are beyond our control, including:

- the FDA's and foreign regulatory agencies' acceptance of our parameters for regulatory approval relating to FMX101, FMX103 and our other product candidates, including our proposed indications, primary endpoint assessments, primary endpoint measurements and regulatory pathways;

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the FDA's and foreign regulatory agencies' acceptance of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from preclinical studies or clinical trials;

- the FDA's and foreign regulatory agencies' acceptance of the sufficiency of the data we collected from our preclinical studies and early clinical trials of FMX101 and FMX103 to support the submission of an NDA or similar foreign regulatory application without requiring additional preclinical or clinical trials;

- the FDA's and foreign regulatory agencies' willingness to schedule an advisory committee meeting in a timely manner to evaluate and decide on the approval of our NDA or similar foreign regulatory application;

- the recommendation of the FDA and foreign regulatory agencies' advisory committee to approve our application without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;

- the FDA's and foreign regulatory agencies' willingness to grant separate approvals for adults and children, where we may have successful clinical trial results for children but not for adults, or vice versa;

- the FDA's and foreign regulatory agencies' satisfaction with the safety and efficacy of FMX101 and FMX103 or our other product candidates;

- the prevalence and severity of adverse events associated with FMX101, FMX103 and our other product candidates;
- the timely and satisfactory performance by third party contractors of their obligations in relation to our clinical trials, including any future Phase III clinical trials for FMX101 and FMX103;
- our success in educating dermatologists, pediatricians and patients about the benefits, administration and use of FMX101, FMX103 and our other product candidates, if approved;
- our ability to raise additional capital on acceptable terms in order to achieve our goals;
- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments;
- the effectiveness of our marketing, sales and distribution strategy and operations, as well as that of our current and future licensees;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to obtain, protect and enforce our intellectual property rights with respect to FMX101 or our other product candidates; and
- our ability to avoid third party claims of patent infringement or intellectual property violations.

If we fail to achieve these objectives or to overcome the challenges presented above, many of which are beyond our control, in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we may not be able to generate sufficient revenues through the sale of FMX101 or our other product candidates to enable us to continue our business.

We may encounter delays in completing clinical trials for FMX101, FMX103 and our other product candidates and may even be prevented from commencing such trials due to factors that are largely beyond our control.

We have in the past and may in the future experience delays in completing our ongoing clinical trials and in commencing future clinical trials. We have already experienced delays in our Phase III clinical trials with FMX101 for acne, due to quality control issues with certain active ingredients supplied to us by a third party, and in our Phase II clinical trial with FMX102 for impetigo that took place in Israel, due to our difficulty in enlisting a sufficient number of pediatric patients with the necessary severity of the disease to participate in the trial. Such difficulties may arise again in future trials for other indications and for our other product candidates.

We rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. Clinical trials can be delayed or aborted for a variety of other reasons, including delay or failure to:

- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which may be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;

·enlist suitable patients to participate in a trial;

·have patients complete a trial or return for post-treatment follow-up;

·ensure clinical sites observe trial protocol or continue to participate in a trial;

·address any patient safety concerns that arise during the course of a trial;

·address any conflicts with new or existing laws or regulations;

·add a sufficient number of clinical trial sites; or

·manufacture sufficient quantities of the product candidate for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and 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, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including any new drugs or treatments that may be approved for the indications we are investigating.

We may also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, by the FDA or by the applicable foreign regulatory authorities. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in carrying out or completing any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

FMX101, FMX103 and other product candidates may produce undesirable side effects that we may not have detected in our Phase II clinical trials. This could prevent us from gaining marketing approval or market acceptance for this product candidate, or from maintaining such approval and acceptance, and could substantially increase commercialization costs and even force us to cease operations.

FMX101, FMX102, FMX103 and FDX104 have so far been shown in Phase I and Phase II to have no drug-related systemic side effects and only a few cases of mild and temporary skin reactions have been reported, most of which disappeared on their own within 12 weeks from the beginning of the treatment. Nonetheless, in further Phase III clinical trials, which involve large patient populations, and upon commercialization of FMX101,FMX103 or other product candidates, if approved, the clinical exposure of the drugs will be significantly expanded to a wider and more diverse group of patients than those participating in the clinical trials, which may reveal undesirable side effects caused by these products that were not previously observed or reported in the current clinical trials.

The FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if our products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date on which we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties or seizure of our products.

Additionally, in the event we discover the existence of adverse medical events or side effects caused by one of our product candidates, a number of other potentially significant negative consequences could result, including:

- the FDA or foreign regulatory authorities may suspend or withdraw their approval of the product;
- the FDA or foreign regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- the FDA or foreign regulatory authorities may require us to issue specific communications to healthcare professionals, such as letters alerting them to new safety information about our product, changes in dosage or other important information;
- the FDA or foreign regulatory authorities may issue negative publicity regarding the affected product, including safety communications;
- we may be limited with respect to the safety-related claims that we can make in our marketing or promotional materials;
- we may be required to change the way the product is administered, conduct additional preclinical studies or clinical trials or restrict or cease the distribution or use of the product; and

· we could be sued and held liable for harm caused to patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase commercialization costs or even force us to cease operations.

Even if FMX101, FMX103 or our other product candidates receive marketing approval, we may continue to face future developmental and regulatory difficulties. In addition, we are subject to government regulations and we may experience delays in obtaining required regulatory approvals to market our proposed product candidates.

Even if we complete clinical testing and receive approval of any regulatory filing for FMX101, FMX103 or any of our other product candidates, the FDA or applicable foreign regulatory agency may grant approval contingent on the performance of additional costly post-approval clinical trials, risk mitigation requirements and surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our products, if any.

The FDA or applicable foreign regulatory agency may also approve FMX101, FMX103 or any of our other product candidates for a more limited indication or a narrower patient population than we originally requested, or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Furthermore, any such approved product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping.

If we fail to comply with the regulatory requirements of the FDA or other applicable foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

·suspend or impose restrictions on operations, including costly new manufacturing requirements;

·refuse to approve pending applications or supplements to applications;

·suspend any ongoing clinical trials;

·suspend or withdraw marketing approval;

·seek an injunction or impose civil or criminal penalties or monetary fines;

·seize or detain products;

·ban or restrict imports and exports;

·issue warning letters or untitled letters;

·suspend or impose restrictions on operations, including costly new manufacturing requirements; or

·refuse to approve pending applications or supplements to applications.

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

Even if FMX101, FMX103 or our other product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.

Even if we obtain FDA or foreign regulatory approvals for FMX101, FMX103 or any of our other product candidates, the commercial success of such products will depend significantly on their broad adoption and use by dermatologists, pediatricians and other physicians for approved indications, including, in the case of FMX101 and FMX103, for the treatment of moderate-to-severe acne, moderate-to-sever rosacea and other therapeutic indications that we may seek to pursue.

Moreover, if the treatment of acne with FMX101 or rosacea with FMX103 is deemed to be an elective procedure, the cost of which is borne by the patient, it will not be reimbursable through government or private health insurance.

The degree and rate of physician and patient adoption of FMX101, FMX103 and any of our other product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- the safety and efficacy of our product as compared to existing therapies for those indications;
- the prevalence and severity of adverse side effects;
- patient satisfaction with the results and administration of our product and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- patient demand for the treatment of moderate-to-severe acne and rosacea or other indications;
- overcoming biases of physicians and patients towards topical treatments for moderate-to-severe acne, rosacea or other indications and their willingness to adopt new therapies for these indications;
- the cost of treatment in relation to alternative treatments, the extent to which these costs are reimbursed by third party payors, and patients' willingness to pay for our products;
- proper training and administration of our products by dermatologists, pediatricians and medical staff;

- the revenues and profitability that our products will offer physicians as compared to alternative therapies; and
- the effectiveness of our sales and marketing efforts, especially the success of any targeted marketing efforts directed toward dermatologists, pediatricians, other physicians, clinics and any direct-to-consumer marketing efforts we may initiate.

If FMX101, FMX103 or any of our other product candidates are approved for use but fail to achieve the broad degree of physician adoption and market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected.

Our ability to market FMX101 and FMX103, if approved, may be limited to use for the treatment of moderate-to-severe acne or moderate-to-severe rosacea, respectively, in the U.S., and if we want to expand the indications for which we may market FMX101 or the territories in which we may market these products, we will need to obtain additional regulatory approvals, which may not be granted.

We plan to seek regulatory approval in the U.S. for FMX101 and FMX103 for the treatment of moderate-to-severe acne and moderate-to-severe rosacea, respectively, in the U.S. If FMX101 is approved, the FDA will likely restrict our ability to market or advertise FMX101 and/or FMX103 for other indications, which could limit physician and patient adoption. We may seek to promote and commercialize our products, FMX101 and FMX103, in Europe as well, by applying for marketing approval from the European Medicines Agency, or EMA, or in other jurisdictions, or we may develop new or additional uses or protocols for FMX101and/or FMX103 in the future, but we may not receive the clearances required to do so. If we proceeded to submit for marketing approval in Europe we would likely be required to conduct additional clinical trials or studies to support approvals for such additional jurisdictions or indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside the U.S., it is required that a product receives pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. In other countries, product approval depends on showing superiority to an approved alternative therapy. This may lead to conducting complex clinical trials that require additional significant resources.

None of our products are currently approved for sale in any jurisdiction, including the U.S. or any international markets. If we fail to comply with regulatory requirements in the U.S. or any international market we decide to enter, or to obtain and maintain required approvals, or if regulatory approvals in the U.S. or the relevant international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Marketing approval in one jurisdiction does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain a marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for FMX101 and FMX103. This would reduce our target market and limit the full commercial potential of FMX101 and FMX103.

If we are not successful in developing, acquiring regulatory approval for and commercializing additional product candidates beyond FMX101 or FMX103, our ability to expand our business and achieve our strategic objectives will be impaired.

Although we will devote a substantial portion of our resources on the continued clinical testing and potential approval of FMX101 for the treatment of moderate-to-severe acne and FMX103 for the treatment of moderate-to-severe rosacea, another key element of our strategy is to discover, develop and commercialize a portfolio of products based on our proprietary foam platforms to serve additional therapeutic markets. We are seeking to do so through our internal research programs, but our resources are limited, and those that we have are geared towards clinical testing and seeking regulatory approval for FMX101 and FMX103. We may also explore strategic collaborations for the development or acquisition of new products, but we may not be successful in entering into such relationships. While we have commenced Phase III clinical trials for our lead product candidate, FMX101 for the treatment of moderate-to-severe acne, and plan to commence a Phase III clinical trial for FMX103 for the treatment of rosacea, all of our other potential product candidates remain in similar or earlier stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

·the research methodology used may not be successful in identifying potential product candidates;

·competitors may develop alternatives that render our product candidates obsolete or less attractive;

·product candidates we develop may nevertheless be covered by third parties' patents or other proprietary rights;

- a product candidate may in a subsequent trial be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;

- a product candidate may not be accepted as safe and effective by patients, the medical community or third party payors, if applicable;

- intellectual property rights, such as patents, which are necessary to protect our interests in a product candidate, may be difficult to obtain or unobtainable; and

- intellectual property rights of third parties may potentially block our entry into certain markets, or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing FMX101 and FMX103.

Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration and expansion.

If we receive marketing approval, the expected indication of FMX101 will be moderate-to-severe acne and the expected indication of FMX103 will be moderate-to-severe rosacea. The facial aesthetic market in general, and the market for acne treatments in particular, is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. FMX101, if approved, may face significant competition from other acne products, including oral drugs such as Solodyn, Doryx, Dynacin, Acticlate and Minocin, and topical anti-acne drugs such as Acanya, Ziana, Epiduo, Benzaclin, Aczone and Differin. FMX103, if approved, may face significant competition from other rosacea products, including oral drugs such as Oracea®, and topical anti-rosacea drugs such as Metrogel, Soolantra and Finacea, all of which have been approved for marketing and are available to consumers. If approved, FMX101 and FMX103 may also compete with non-prescription anti-acne and rosacea products and unapproved and off-label treatments. To compete successfully in the acne and rosacea treatment markets, we will have to demonstrate that FMX101 is safe and effective for the treatment of moderate-to-severe acne and FMX103 is safe and effective for the treatment of moderate-to-severe rosacea, and that they do not infringe the intellectual property rights of any third parties. Competing in the acne and rosacea markets could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more acne products and procedures available for use in international markets than are approved for use in the U.S. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we may face more competition in these markets than in the U.S.

In addition, even if we are able to commercialize our product candidates, we may not be able to price them competitively with current standard of care products or their price may drop considerably due to factors outside our control. If this happens or the price of materials and manufacture increases dramatically, our ability to continue to operate our business would be materially harmed and we may be unable to commercialize FMX101 or FMX103 successfully.

Other pharmaceutical companies may develop competing products for acne, rosacea and other indications we are pursuing and enter the market ahead of us.

Other pharmaceutical companies are engaged in developing, patenting, manufacturing and marketing healthcare products that compete with those that we are developing. These potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities.

Several of these potential competitors are privately-owned companies that are not bound by public disclosure requirements and closely guard their development plans, marketing strategies and other trade secrets. Publicly-traded pharmaceutical companies are also able to maintain a certain degree of confidentiality over their pipeline developments and other sensitive information. As a result, we do not know whether these potential competitors are already developing, or plan to develop, foam-based or other topical treatments for acne, rosacea, impetigo or other indications we are pursuing, and we will likely be unable to ascertain whether such activities are underway in the future. These potential competitors may therefore introduce competing products without our prior knowledge and without our ability to take preemptive measures in anticipation of their commercial launch.

In this regard we became aware at the end of 2014 that an active pharmaceutical ingredient and drug product intermediate manufacturer, Hovione, has submitted an IND for Phase I and II clinical trials of a new topical product containing minocycline for the treatment of inflammatory skin disease including acne and rosacea. Hovione is a privately-held company and we do not know if they have commenced a clinical trial for such new topical minocycline product. Hovione also currently manufactures and supplies Foamix with pharmaceutical-grade minocycline for use in FMX101, FMX103 and other products. Although we have not experienced unique difficulties in procuring minocycline from Hovione, we could experience such difficulties in the future. During 2015 we became aware that another company, BioPharmX Corporation (NYSE MKT: BPMX), is developing a topical hydrophilic gel containing minocycline for the treatment of acne, known as BPX-01, for which BioPharmX has announced Phase IIa clinical trials results. If ultimately approved and commercialized in the U.S., such products would become direct competitors of FMX101, FMX103 and other potential pipeline products.

Furthermore, such potential competitors may enter the market before us, and their products may be designed to circumvent our granted patents and pending patent applications. Potential competitors may also challenge, narrow, invalidate or seek to design around our granted patents or our patent applications, and such patents and patent applications may fail to provide adequate protection for our product candidates.

We have agreements with third party licensees to develop new product candidates for them utilizing our foam technology, and our ability to benefit from such product candidates could be impaired or delayed if our licensees' efforts to develop and commercialize these product candidates are unsuccessful.

In parallel to our core business focused on the development of FMX101, FMX103 and other product candidates, we are pursuing development and license agreements with various pharmaceutical companies for the development and commercialization of product candidates that combine our proprietary technology with the licensees' drugs for the treatment of various indications. These license agreements generally provide rights to the licensees for a single active pharmaceutical ingredient, and grant the licensee exclusivity in the development and commercialization of the specific licensed product candidates incorporating such active pharmaceutical ingredient. Our entitlement to contingent payments and royalties from such potential product candidates is therefore dependent upon the licensees' performance of their responsibilities and their continued cooperation in developing and commercializing the potential product candidates.

Our licensees may not cooperate with us or perform their obligations under our agreements with them. Furthermore, the obligations of the licensees under such agreements are, for the most part, limited to 'commercially reasonable efforts,' and they do not face penalties or other repercussions for failing to develop or commercialize the relevant product candidates within the designated timetable other than potentially forfeiting their rights to the relevant product candidate and assigning such rights to us. However, there is no guarantee that we will be able to develop, manufacture or commercialize successfully any such product candidate assigned to us. We cannot control the scope or timing of the resources that will be devoted by our licensees to performing their responsibilities under our agreements with them. Our licensees may choose to pursue alternative technologies in preference to those being developed with us. Several of these agreements may also be terminated for convenience by the licensee. The development and commercialization of these licensed product candidates as well as the anticipated contingent payments and royalties we hope to generate from them will be delayed or never obtained if the licensees fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements, or if they breach their agreements with us. Disputes with our licensees could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

We have granted several of our licensees the right to commercialize the licensed products for any indication, including acne and rosacea, which may allow them to compete against us using our own technology.

The licenses we granted to several of our licensees, with whom we are developing certain topical products based on our technology and the licensees' proprietary drugs, allow them to commercialize the developed products for any topical application, and not only for the specific indication for which each product was originally intended. If any such licensed products prove to be effective for moderate-to-severe acne, rosacea or any other indication that we are pursuing with FMX101, FMX103 or other product candidates, we may face competition from these licensed products, as the licensees are not bound by any non-compete restrictions.

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

In both the U.S. and other countries, sales of our products, if approved for marketing, 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 U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. Any reduction in reimbursement that results from federal legislation or regulation may also result in a similar reduction in payments from private payors, as private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, or the Affordable Care Act, a law intended, among other things, to broaden access to health insurance and reduce or constrain the growth of healthcare spending. The Affordable Care Act increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100.0% of AMP.

On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. These regulations became effective on April 1, 2016.

Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by up to 2% per fiscal year under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Due to the Bipartisan Budget Act of 2015, these reductions will remain in effect until 2025 unless additional action is taken by Congress.

It is unclear how the Affordable Care Act and other laws ultimately will be implemented. Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed. Thus, while the full impact of the Affordable Care Act, or any law replacing elements of it, on our business remains unclear, if we ever obtain regulatory approval and commercialization of one or more of our product candidates, these laws may result in reductions in healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have also 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 our product candidates may be.

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

It will be difficult for us to profitably sell FMX101, FMX103 or our other product candidates if reimbursement for these products is limited by government authorities and third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of FMX101, FMX103 and our other product candidates, if approved, will depend on the reimbursement policies of government authorities and third-party payors. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for FMX101 or FMX103, or, if reimbursement is available, the level of reimbursement.

Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. In addition, third-party payors are likely to impose strict requirements for reimbursement in order to limit off-label use of a higher priced drug. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

·a covered benefit under its health plan;

·safe, effective and medically necessary;

·appropriate for the specific patient;

·cost-effective; and

·neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, profitably or at all, even if approved.

Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of FMX101, FMX103 or any of our other product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

·changes to manufacturing methods;

. recall, replacement, or discontinuance of one or more of our products; and

·additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

We are currently investing the majority of our resources towards (i) completing Phase III clinical trials for FMX101 during 2017, filing an NDA in 2018 and developing a commercialization plan for such product candidate that we will initiate during 2018, (ii) bringing FMX103 to commence Phase III clinical trials in 2017 and (iii) continuing the development and advancement of the clinical trials of our other product candidates. However, we may not have sufficient funds to carry out and complete all of these plans, and may need to raise additional funds for such purposes.

We anticipate that we will continue to expend substantial resources for the foreseeable future for the clinical development of FMX101, FMX103, and the development of other indications and product candidates. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any of our product candidates.

We believe that the net proceeds from our initial and follow-on public offerings will allow us to fund our operating expenses and capital expenditure requirements throughout the Phase III clinical trials for our lead product candidate, FMX101, which we expect to complete in 2017. Such proceeds should also fund our Phase III clinical program for FMX103, which we expect to commence in 2017. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations or additional license arrangements. Such financings may result in dilution to shareholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the results of the clinical trials of our products candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms of and timing of such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs associated with evaluation of our product candidates;
- the costs associated with evaluation of third party intellectual property;
- the costs associated with obtaining and maintaining licenses;
- the costs associated with obtaining, protecting and enforcing intellectual property, such as costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for FMX101, FMX103 or any of our other product candidates;
- delay, limit, reduce or terminate our research and development activities; or

- delay, limit, reduce or terminate our establishment of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize FMX101, FMX103 or any of our other product candidates.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing shareholders will be diluted and the terms of any new equity securities may have a preference over our ordinary shares. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures or specified financial ratios, any of which could restrict our ability to commercialize our product candidates or operate as a business.

We have a limited operating history and have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We have only four product candidates that have completed any clinical trials and have no sales, which, together with our limited operating history, make it difficult to assess our future commercial viability.

We are a small clinical-stage specialty pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2003. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry.

To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenues from product sales relating to FMX101, FMX103 or any of our other product candidates. We have generated revenues only from service payments, and contingent payments paid towards or in the course of projects carried out under several of our development and license agreements with various pharmaceutical companies. We have also received (and continue to receive) royalty payments with respect to Finacea®, a prescription foam product that we developed in collaboration with Bayer.

We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We have recorded a net loss of $29.3 million, $16.5 million and $11.5 million for the twelve months ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $75.6 million and had a working capital surplus of $111.7 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, and seek regulatory approvals for, FMX101, FMX103 and our other product candidates, and begin to commercialize such product candidates.

Our ability to achieve revenues and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and successfully manufacture, market and commercialize our products. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of our ordinary shares and our ability to raise capital and continue operations.

We currently contract with third party subcontractors and suppliers for certain compounds and components necessary to produce FMX101 and FMX103 for clinical trials and expect to continue to do so to support commercial scale production if one or more of such product candidates is approved. This increases the risk that we will not have sufficient quantities of FMX101 and FMX103 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third party subcontractors and suppliers for certain compounds and components necessary to produce FMX101and FMX103 for our clinical trials, including minocycline and other active ingredients, excipients used in the formulation of the foam, delivery apparatus comprising canisters, valves and propellants. We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements if FMX101 and FMX103 or any of our other product candidates is approved for marketing by the FDA or foreign regulatory authorities.

Reliance on third party subcontractors and suppliers entails a number of risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing or supply agreement by the third party, the possibility that the supply is inadequate or delayed , the risk that the third party may enter the field and seek to compete and may no longer be willing to continue supplying, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third party subcontractors and suppliers may not be able to comply with cGMP or quality system regulation, or QSR, or similar regulatory requirements outside the U.S. If any of these risks transpire, we may be unable to timely retain alternate subcontractors or suppliers on acceptable terms and with sufficient quality standards and production capacity, which may disrupt and delay our clinical trials or the manufacture and commercial sale of our product candidates, if approved.

Our failure or the failure of our third party subcontractors and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates that we may develop.

Although we have not experienced unique difficulties in procuring compounds and components for FMX101, FMX103, FDX104 or any other product candidates, and while we are acting to secure additional suppliers for such compounds and components, we could experience such difficulties in the future.

We will rely on third parties and consultants to assist us in conducting our trials and studies. If these third parties or consultants will not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently perform all aspects of our preclinical studies and clinical trials. We will rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to assist us in conducting our Phase III clinical trials for FMX101, FMX103 and studies and clinical trials for our other product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we will have limited ability to control the amount or timing of resources that they devote to our programs.

Although we rely on these third parties to conduct certain aspects of our Phase III clinical trials and other studies and clinical trials, we remain responsible for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as current good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We also rely on our consultants to assist us in the execution, including data collection and analysis of our clinical trials.

In addition, the execution of clinical trials and preclinical studies, and the subsequent compilation and analysis of the data produced, will require coordination among these various third parties. In order for these functions to be carried out effectively and efficiently, it will be imperative that these parties communicate and coordinate with one another, which may prove difficult to achieve. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Our agreement with these third parties may inevitably enable them to terminate such agreements upon reasonable prior written notice under certain circumstances.

If the third parties or consultants that assist us in conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or 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 trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for the product candidates being tested in such trials, and will not be able to, or may be delayed in our efforts to, successfully commercialize these product candidates.

We have no experience manufacturing our product candidates at full commercial scale. If our product candidates are approved, we intend to outsource our manufacturing to third parties, and will face certain risks associated with such outsourcing.

We have a small-scale integrated research, development and testing facility located at our corporate headquarters in Rehovot, Israel. However, we have not equipped our facility with manufacturing capabilities other than small scale manufacture, and do not currently plan to do so. We do not have experience in manufacturing our product candidates at commercial scale, and if our product candidates are approved, we will outsource all or a significant portion of the manufacturing of our products to third parties, including our drug substances and finished dose forms. Reliance on third parties to manufacture our products entails various risks, including the possibility of increased costs associated with the large- scale production of our products. These risks are similar to those involved in our current use of subcontractors and suppliers for certain compounds and components necessary to produce FMX101, FMX103 and any other of our other product candidates, as explained above.

If we are unsuccessful in outsourcing our manufacturing to third parties who are compliant with regulatory requirements, we may encounter delays or additional costs in achieving our commercialization objectives, which could materially damage our business and financial position.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize FMX101, FMX103 or any other of our other product candidates, if approved, or generate product revenues.

We currently have limited marketing capabilities and no sales organization. To commercialize FMX101, FMX103 or any other of our other product candidates, if approved, in the U.S. and other jurisdictions we may seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements

with third parties to perform these services, and we may not be successful in doing so. If FMX101 or FMX103 receive regulatory approval, we expect to market them in the U.S. through a specialized internal sales force or a combination of our internal sales force and distributors, which will be expensive and time-consuming.

There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize FMX101, FMX103 or any of our other product candidates.

If we are not successful in commercializing FMX101, FMX103 or any of our other product candidates, either on our own or through collaborations with one or more third parties, our revenues will suffer and we will incur significant additional losses.

To establish our sales and marketing infrastructure and manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this expansion.

As of December 31, 2016, we had 68 employees. We will need to continue to expand our managerial, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize FMX101, FMX103 and any other product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

· manage our clinical trials effectively;

· identify, recruit, retain, incentivize and integrate additional employees;

· manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and

· continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated expansion, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion could delay the execution of our development and strategic objectives, or disrupt our operations.

We currently develop our clinical drug products exclusively in one research and development facility and may utilize this facility in the future to support commercial production if our product candidates are approved. If this or any future facility or our equipment were to be damaged or destroyed, or if we experience a significant disruption in our operations for any other reason, our ability to continue to operate our business would be materially harmed.

We currently research and develop our product candidates primarily in our laboratory located in Rehovot, Israel.

If this or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of our research and development facility is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to manufacture our products as promptly as our prospective customers will likely expect, or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

Currently, we maintain insurance coverage totaling $1.2 million against damage to our property and equipment and $5.0 million in workers compensation coverage, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

If product liability lawsuits are brought against us, we may incur substantial liabilities that may not be fully covered by our insurance policies and we may be required to limit commercialization of any of our other products we develop.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly

causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

·decreased demand for FMX101, FMX103 or any of our other product candidates or products we develop;

·injury to our reputation and significant negative media attention;

·withdrawal of clinical trial participants or cancellation of clinical trials;

·costs to defend the related litigation, which may be only partially recoverable even in the event of successful defense;

·a diversion of management's time and our resources;

·substantial monetary awards to trial participants or patients;

·regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;

·loss of revenues; and

·the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of FMX101, FMX103 or any other product we may develop. We currently carry general third party liability insurance up to an amount of $10 million per annum. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, 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. If and when we obtain approval for marketing of one or more of FMX101, FMX103 or any other product we may develop, we intend to expand our insurance coverage to include their sale; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop FMX101, FMX103 or any of our other product candidates, conduct our clinical trials and commercialize FMX101, FMX103 or any of our other products we develop.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly our Chief Executive Officer, as well as our senior technologists and scientists. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of FMX101, FMX103 or any of our other product candidates.

Although we have not historically experienced unique difficulties in attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the pharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We have incurred, and will continue to incur significant increased costs as a result of operating as a public company in the U.S., and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the U.S., we are subject to an extensive regulatory regime, requiring us to maintain various internal controls and to prepare and file periodic and current reports and statements, including reports on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. Complying with these requirements is costly and time consuming. In the event that we are unable to demonstrate compliance with our obligations as a public company in the U.S. in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the U.S. Securities and Exchange Commission, or the NASDAQ Global Market, and investors may lose confidence in our operating results and the price of our ordinary shares could decline.

Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting, and as long as we remain an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we are exempt from the requirement to have an independent registered public accounting firm perform such audit. Accordingly, no such opinion was expressed. Once we cease to qualify as an "emerging growth company," our independent registered public accounting firm will need to attest to our management's annual assessment of the effectiveness of our internal controls over financial reporting, which will entail additional costs and expenses.

Our business involves the use of hazardous materials and we and our third party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third party subcontractors' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including minocycline and doxycycline, key components of our product candidates, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We are licensed by the Israeli Ministry of Health to manufacture small batches of product in topical dose form for Phase I and II clinical trials. In some cases, these hazardous materials are stored at our and our subcontractors' facilities pending their use and disposal.

Despite our efforts, we cannot eliminate the risk of contamination. This could cause an interruption of our commercialization efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our subcontractors and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

We may in the future be subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

While we do not expect that FMX101, FMX103 or any other of our other product candidates, if approved, will subject us to the various U.S. federal and state laws intended to prevent health care fraud and abuse, we may in the future become subject to such laws. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal and state health care programs and substantial civil and criminal penalties.

The federal False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Although we believe the market for acne and rosacea therapies is less vulnerable to unfavorable economic conditions due to the significant discomfort and distress that these conditions inflict, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. We currently have very limited visibility regarding the prospects of FMX101, FMX103 or our other product candidates becoming eligible for reimbursement by any government or third party payor and the possible scope of such reimbursement, and we must assume that demand for these product candidates may be tied to discretionary spending levels of our targeted patient population.

A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for FMX101, FMX103 or any of our other product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Exchange rate fluctuations between the U.S. dollar and the Israeli shekel may negatively affect our earnings.

The dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in Israeli shekels. As a result, we are exposed to the risks that the shekel may appreciate relative to the dollar, or, if the shekel instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the shekel, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation or deflation in Israel or the rate of devaluation or appreciation of the shekel against the dollar. For example, the rate of appreciation of the shekel against the dollar was 1.5% and 0.3% in 2016 and 2015, respectively, which was compounded by deflation in Israel at a rate of -0.2% and -1.0%, respectively. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

Risks Related to Our Intellectual Property

If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to FMX101, FMX103 or any of our other product candidates are not adequate, we may not be able to compete effectively and we otherwise may be harmed.

Our commercial success depends in part on our ability to obtain and maintain patent protection and other intellectual property rights and to utilize trade secret protection for our intellectual property and proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection and confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to FMX101, FMX103 and our other development programs. Limitations on the scope of our intellectual property rights may limit our ability to prevent third parties from designing around such rights and competing against us. For example, our patents do not claim a new compound. Rather, the active pharmaceutical ingredients of our products are existing compounds and our granted patents and pending patent applications are directed to, among other things, novel formulations of these existing compounds that are dispensed as a foam. Accordingly, other parties may compete with us, for example, by independently developing or obtaining competing topical formulations that design around our patent claims, but which may contain the same active ingredients, or by seeking to invalidate our patents. Moreover any disclosure to or misappropriation by third parties of our confidential proprietary information, unless we have sufficient patent and/or trade secret protection and we are able to enforce such rights successfully, could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

We currently have several granted patents related to FMX101, FMX103 and our other product candidates in the U.S., which are expected to remain in effect until 2030. These patents relate to a composition of matter comprising a claim to a formulation of a tetracycline antibiotic which can include minocycline or doxycycline, and therefore may be less protective than patents that claim a new drug. We also have patent applications claiming compositions of matter, which relate to FMX101, FMX103 and our other product candidates, pending in each of the following international markets, Australia, Brazil, Canada, China, the European Union, India, Israel and Mexico.

As of December 31, 2016, we had 149 granted patents and over 50 patent applications pending worldwide covering our various foam-based platforms and other technology. However, the patent applications that we own or license may fail to result in granted patents in the U.S. or foreign jurisdictions, or if granted the patent claims may fail to prevent a potential infringer from marketing its product or be deemed invalid and unenforceable by a court. Competitors in the field of topically-administered therapies comprising an active ingredient in foam presentation have created a

substantial amount of scientific publications, patents and patent applications and other materials relating to their technologies. Our ability to obtain and maintain valid and enforceable patents depends on various factors, including interpretation of our technology and the prior art and whether the differences between them allow our technology to be patentable. Patent applications and patents granted from them are complex, lengthy and highly technical documents that are often prepared under very limited time constraints and may not be free from errors that make their interpretation uncertain. The existence of errors in a patent may have a materially adverse effect on the patent, its scope and its enforceability. Our pending patent applications may not issue, and the scope of the claims of patent applications that do issue may be too narrow or inadequate to protect our competitive advantage. Also, our granted patents may be subject to challenges or construed in a way that may not provide adequate protection.

Even if these patents do successfully issue, third parties may challenge the validity, enforceability or scope of such granted patents or any other granted patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within 9 months from the publication of their grant. Also, patents granted by the U.S. Patent and Trademark Office, or USPTO, may be subject to review, reexamination and other challenges. Changes to the patent laws of the U.S. in 2012 provide additional procedures for third parties to challenge the validity of patents issuing from patent applications including post-grant review, which generally applies to patents first filed after March 15, 2013. A post-grant review petition must be filed on or prior to the date which is 9 months after the patent is granted. The procedures also expand and reform the proceedings for challenging issued patents on grounds of prior art and publications, also known as inter partes review or IPR. For patents filed after March 15, 2013, a petition for IPR may be filed the later of 9 months after grant of the patent or after a post-grant review proceeding on the patent has terminated. For patents filed prior to March 15, 2013, the rules regarding IPR filing remain unchanged and an IPR petition may be filed any time following issuance of the patent.

Furthermore, efforts to enforce our patents could give rise to challenges to their validity or unenforceability in court proceedings. If the patents and patent applications we hold or pursue with respect to FMX101, FMX103 or any of our other product candidates are challenged, it could threaten our competitive advantage for FMX101, FMX103 or any of our other product candidates. Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, we may need to evaluate third party intellectual property rights and, if appropriate, to seek licenses for such third party intellectual property or to challenge such third party intellectual property, which may be costly and may or may not be successful, which could also have a material adverse effect on the commercial potential for FMX101, FMX103 and any of our other product candidates.

Further, if we encounter delays in our clinical trials, the period of time during which we could market FMX101, FMX103 or any of our other product candidates under patent protection could be reduced.

Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to (i) file any patent application related to FMX101, FMX103 or any of our other product candidates or (ii) conceive and invent any of the inventions claimed in our patents or patent applications.

Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be invoked by a third party, or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO under the new first-to-file system before we did could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party.

The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the U.S. resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. Because of a lower evidentiary standard in certain USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence may be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. USPTO statistics indicate that a high rate of challenged claims are being invalidated in these USPTO procedures.

Even where patent, trade secret and other intellectual property laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and our competitors have intellectual property portfolios of their own, some of which are substantial. An unfavorable outcome could have a material adverse effect on our business and could result in the challenged patent or one or more of its claims being interpreted narrowly or invalidated, or one or more of our patent applications may be not be granted.

We also rely on trade secret protection and confidentiality agreements to protect our know-how, data and information prior to filing patent applications and during the period before they are published. We further rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

In an effort to protect our trade secrets and other confidential information, we incorporate confidentiality provisions in all our employees' agreements and require our consultants, contractors and licensees to which we disclose such information to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that confidential information, as defined in the agreement and disclosed to the individual by us during the course of the individual's relationship with us, be kept confidential and not disclosed to third parties for an agreed term. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could significantly affect our competitive position and we could lose our trade secrets or they could become otherwise known or be independently discovered by our competitors. Also, to the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Additionally, others may independently develop the same or substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information. Any of the foregoing could deteriorate our competitive advantages, undermine the trade secret and contractual protections afforded to our confidential information and have material adverse effects on our business.

Changes in U.S. or foreign patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other companies in the markets in which we participate, our success is heavily dependent on intellectual property, particularly patents. The strength of patents in the pharmaceutical field involves complex legal and scientific questions and in the U.S. and many foreign jurisdictions patent policy and case law also continues to evolve and change and the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret or expand on existing law in ways affecting the scope or validity of granted patents, or both. Particularly in recent years in the U.S., there have been several major legislative developments and court decisions that have affected patent laws in significant ways and there may be more developments in the future that may weaken or undermine our ability to obtain patents or to enforce our existing and future patents.

We have agreed to share ownership in certain patents that may result from our development and license agreements with certain major pharmaceutical companies, which may detract from our rights to such patents.

We have agreed with several of the pharmaceutical companies with whom we are developing certain topical products, based on our foam technology and the licensees' active ingredients, to jointly own and have an undivided interest in patents that arise from the relevant projects, where the licensee made its own material contributions to the invention. In certain agreements, we have further agreed that inventions achieved exclusively or primarily by the licensees in the course of the development without significant contribution by us will be owned solely by them, and they will be allowed to file patent applications covering such inventions without our participation.

We have granted certain licensees the right to provide input during the prosecution of licensed patent applications. We have further granted certain licensees the primary right to enforce several of our existing patents, which we have licensed to these licensees to allow them to commercialize our jointly-developed product, in the event that any infringement of the licensed patents adversely affects the licensees' ability to utilize the licenses for the purpose they were granted. Such rights may detract from our rights and title to such patents. In addition, any negative proceedings against our technology could impact any or all of our licensees, and we may be contractually responsible for the payment of certain claims and losses as a result of such impact.

If we infringe or are alleged to infringe or otherwise violate intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of topical and oral drugs for the treatment of acne, impetigo, rosacea, chemotherapy-induced rash and other indications have developed large portfolios of patents and patent applications relating to our business. In particular, there are patents held by third parties that relate to the treatment with minocycline-based and doxycycline-based products for indications we are pursuing with our product candidates, namely FMX101, FMX103 and any other of our other product candidates. There may be granted patents that could be asserted against us in relation to such product candidates. There may also be granted patents held by third parties that may be infringed or otherwise violated by our other product candidates and activities, and we do not know whether or to what extent we are infringing or otherwise violating third party patents. There may also be third party patent applications that if approved and granted as patents may be asserted against us in relation to FMX101, FMX103 or any of our other product candidates or activities. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages and legal fees. Further, if a patent infringement suit were brought against us, we could be temporarily or permanently enjoined or otherwise forced to stop or delay research, development, manufacturing or sales of the product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been and there currently is substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, review, re-examination or other post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or any future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings and their outcome could impair our ability to compete in the marketplace and impose a substantial financial burden on us. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, several of our employees were previously employed at universities or other pharmaceutical companies, including potential competitors. While we take steps to prevent our employees from using the proprietary information or know-how of others that is not in the public domain or that has not already been independently developed by us earlier, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we do not succeed with respect to any such claims, in addition to paying monetary damages and possible ongoing royalties, we may lose valuable intellectual property rights or personnel.

If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify "Foamix", and have registered these trademarks in the U.S. and Israel. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third party infringement or unauthorized use. This can be expensive and burdensome, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation review, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or licensees. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or licensees, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our ordinary shares could be significantly harmed.

We may not obtain intellectual property rights or otherwise be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. We primarily file patent applications in the U.S., and may file in some other selected jurisdictions on a case-by-case basis. As a result, our intellectual property rights in countries outside the U.S. are generally less extensive than those in the U.S. In addition, the laws of some foreign countries and jurisdictions, particularly of certain developing countries and jurisdictions, do not protect intellectual property rights to the same extent as federal and state laws in the U.S., and these countries and jurisdictions may limit the scope of what can be claimed, and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but protection and enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Moreover, competitors or others may raise legal challenges to our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Further, third parties may prevail in their claims against us, which could potentially result in the award of injunctions or substantial damages against us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

We have received notices of opposition to our European patent no. 1556009

Two notices of opposition have been filed with regard to our patent entitled "Cosmetic and Pharmaceutical Foam", which relates to an alcohol-free foamable pharmaceutical or cosmetic carrier and its use. The notices of opposition were filed by Guderma and Henkel in Germany, with supporting documentation prior to the close of the opposition period on September 24, 2015. We have defended these proceedings, and at a hearing on January 23, 2017 the Opposition Division of the Europen Patent Office, or EPO, decided to maintain the patent in amended form. One or both of the unsuccessful opponents may file an appeal. The deadline for doing so depends on when the Opposition Division issues its reasoned decision in writing. In the event of an appeal, the opposition proceedings may ultimately result in such patent either being upheld as decided by the Opposition Decision; or in the patent being narrowed further; or in the patent being cancelled. The opposition documents are available through the online EPO file for the patent. Although the patent involved is believed by Foamix to be of no material interest to our lead product candidates, it may be of interest in relation to one or more of our licensed products. We are unable to predict what will be the effect of the opposition proceedings or outcome of an appeal, which may potentially have a negative impact on the future commercialization of one or more licensed products.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

We generally enter into non-competition agreements as part of our employment agreements with our employees. These agreements generally prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period. 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 labor courts place emphasis on freedom of employment and 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 protection of a company's trade secrets or other intellectual property.

Risks Related to Our Ordinary Shares

We do not know whether a market for our ordinary shares will be sustained and as a result it may be difficult for holders of our ordinary shares to sell their shares.

Although our ordinary shares are quoted on the NASDAQ Global Market, an active trading market for our shares may not be sustained. The lack of an active market may impair holders of our ordinary shares ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of our shares, and may cause the trading price of our ordinary shares to be more volatile. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

The market price of our ordinary shares may be subject to fluctuation and holders of our ordinary shares could lose all or part of their investment.

The stock market in general has been, and the market price of our ordinary shares in particular will likely be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our ordinary shares on the NASDAQ Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our products;
- the mix of products that we sell and related services that we provide;
- the success or failure of our licensees to develop, obtain approval for and commercialize our licensed products, for which we are entitled to contingent payments and royalties;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for FMX101, FMX103 or our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us, including patent opposition and review proceedings before national patent offices;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts and we do not have commitments from them to write research reports about us. The price of our ordinary shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Future sales of our ordinary shares could reduce the market price of our ordinary shares.

If our shareholders, particularly our directors and their affiliates or our executive officers, sell a substantial number of our ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. The perception in the public market that our shareholders might sell our ordinary shares could also depress the market price of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities. In addition, our sale of additional ordinary shares or similar securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities, and may cause holders of our ordinary shares to lose part or all of their investment.

The significant share ownership position of affiliates of our co-founders, Dr. Dov Tamarkin and Meir Eini, may limit your ability to influence corporate matters.

Tamarkin Medical Innovation Ltd., a company beneficially owned by Dr. Dov Tamarkin, or Tamarkin, our co-founder and chief executive officer, beneficially owns or controls, directly or indirectly, 7.6% of our outstanding ordinary shares, and Meir Eini Holdings Ltd., a company beneficially owned by Meir Eini, or Eini, our co-founder and chief innovation officer, beneficially owns or controls, directly or indirectly, 8% of our outstanding ordinary shares, as of December 31, 2016. Accordingly, Tamarkin and Eini are able to significantly influence, though not independently determine, the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. Tamarkin's and Eini's interests may not be consistent with those of our other shareholders. In addition, Tamarkin's and Eini's significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our ordinary shares.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our share capital, nor do we anticipate paying any cash dividends on our share capital in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares will be investors' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes.

As a foreign private issuer, we are permitted to follow, and are following, certain home country corporate governance practices instead of otherwise applicable SEC and NASDAQ requirements.

As a foreign private issuer, we are permitted to follow, and are following, certain home country corporate governance practices instead of those otherwise required under the NASDAQ Stock Market for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to (i) the quorum requirement for shareholder meetings, and (ii) the requirement for independent director oversight of director nominations. See "Item 16G. Corporate Governance."

We may in the future elect to follow home country practices in Israel (and consequently avoid the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Global Market) with regard to other matters as well, such as (i) the formation of a nominating and governance committee, (ii) separate executive sessions of independent directors and non-management directors and (iii) the requirement to obtain shareholder approval for certain dilutive events such as (a) for the establishment or amendment of certain equity-based compensation plans, (b) issuances that will result in a change of control of the company, (c) certain transactions other than a public offering involving issuances of a 20% or more interest in the company and (d) 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 Global Market may provide less protection to holders of our ordinary shares than what is accorded to investors under the NASDAQ Stock Market rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are not subject to U.S. proxy rules and are exempted from filing certain Exchange Act reports.

As a foreign private issuer we are exempted from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempted from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we

are not required under the Exchange Act to file annual and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act, we are permitted to disclose compensation information for our executive officers on an aggregate basis, rather than an individual, basis and we are generally exempted from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information. These exemptions and leniencies reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our directors or executive officers are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies." Most of such requirements relate to disclosures that we would only be required to make if we cease to be a foreign private issuer in the future. Nevertheless, as a foreign private issuer that is an emerging growth company, we will not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for up to five fiscal years after the date of our initial public offering.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act.

When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Our U.S. shareholders may suffer adverse tax consequences if we are characterized 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 quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) 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 on certain estimates of our gross income and gross assets, our use of proceeds of our initial public offering, and the nature of our business, we believe that we were not classified as a PFIC for the taxable year ended December 31, 2016, and do not anticipate being classified as a PFIC for the taxable year ending December 31, 2017. Because we currently hold, and expect to continue to hold, a substantial amount of cash and cash equivalents and other passive assets used in our business, and because the value of our gross assets is likely to be determined in large part by reference to our market capitalization, a decline in the value of our ordinary shares may result in our becoming a PFIC. Accordingly, we may be considered a PFIC for any taxable year.

If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders (as defined in "Item 10.E. Taxation—U.S. Federal Income Tax Consequences"), and having interest charges apply to distributions by us and the proceeds of share sales. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we are classified as a PFIC. See "Item 10.E. Taxation—U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Considerations."

Risks Related to Our Operations in Israel

Our headquarters, research and development 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 headquarters, and research and development facilities are located in Rehovot, Israel. In addition, the majority of our key employees, 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, its neighboring countries and other organizations. Any hostilities involving Israel or the interruption or curtailment of trade or transport between Israel and its trading partners could adversely affect our operations and results of operations. Further, our operations could be disrupted by the obligations of personnel to perform military reserve service.

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer unless, following consummation of the tender offer, the acquirer would hold at least 98% of the company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

It may be difficult to enforce a judgment of a U.S. court against us, our officers and directors in Israel or the U.S., to assert U.S. securities laws claims in Israel or to serve process on our officers and directors.

We are incorporated in Israel. Most of our executive officers and the majority of our directors listed in this annual report reside outside of the U.S., and most of our assets and most of the assets of these persons are located outside of the U.S. 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 U.S. and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. 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 U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be 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, holders of our ordinary shares may not be able to collect any damages awarded by either a U.S. or foreign court.

The rights and responsibilities of our shareholders are governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our amended articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S.-based companies. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company with regard to such vote or appointment. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. companies.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and development

Our legal and commercial name is Foamix Pharmaceuticals Ltd. (formerly Foamix Ltd.). We were incorporated as a limited liability company under the laws of the State of Israel on January 19, 2003. We are registered with the Israeli

Registrar of Companies. Our registration number is 51-336881-1. Article 3 of our articles of association provides that our objectives are to conduct all types of business as are permitted by law.

Our principal executive offices are located at 2 Holzman St., Weizmann Science Park, Rehovot 7670402, Israel, and our telephone number is +972-8-9316233. Our website is www.foamixpharma.com. The information contained on, or that can be accessed through, our website does not constitute a part of this form and is not incorporated by reference herein. Foamix Pharmaceuticals Inc., our wholly-owned subsidiary, was incorporated on May 6, 2014 under the laws of the State of Delaware, with the intent to serve as our marketing and sales arm in the U.S. Foamix Pharmaceuticals Inc. has been appointed as our agent in the United States and is located at 520 U.S. Highway 22, Suite 305, Bridgewater, New Jersey 08807.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies" such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act.

For information regarding our capital expenditures, see "Item 5.B. Liquidity and Capital Resources."

4.B. Business overview

Who We Are

We are a clinical-stage specialty pharmaceutical company focused on developing and commercializing our proprietary minocycline foam for the treatment of acne, rosacea and other skin conditions. Our lead product candidates, FMX101 for moderate-to-severe acne and FMX103 for treatment of moderate-to-severe papulo-pustular rosacea, are novel topical foam formulations of the antibiotic minocycline. Our clinically and statistically significant Phase II clinical trial results demonstrate that our minocycline foam products, FMX101 and FMX103, provide a fast, effective, and well-tolerated treatment for their respective indications. Currently, oral minocycline and oral doxycycline are the most commonly utilized treatments for moderate-to-severe acne and moderate-to-severe rosacea, respectively. Based on the results demonstrated in our Phase II clinical trials, we believe that FMX101 and FMX103 have the potential to become the new standards of care for moderate-to-severe acne and moderate-to-severe rosacea.

We are currently investing the majority of our efforts and resources to advance our two pivotal Phase III clinical trials for FMX101 and our Phase III clinical program for FMX103 in the U.S. We completed enrollment of our Phase III clinical trials for FMX101 in November 2016. We expect to have top-line results from the blinded stage of these trials in the first half of 2017 and to complete these trials, including their safety extension, by the end of 2017.

We are also developing FMX103, minocycline foam for rosacea. In September 2016, we announced the successful results of a Phase II clinical trial for FMX103 in patients with moderate-to-severe rosacea. We plan to commence a Phase III clinical program of FMX103 for the treatment of moderate-to-severe rosacea in 2017.

In addition, we successfully completed a Phase II clinical trial with FDX104, our proprietary doxycycline foam for the management of moderate-to-severe rash associated with the epidermal growth factor receptor inhibitor, or EGFRI, anticancer treatments. We have also successfully completed a Phase II clinical trial of FMX102, our minocycline foam for the treatment of impetigo, including impetigo caused by methicillin-resistant staphylococcus aureus, or MRSA. While the FMX101 and FMX103 development programs address widespread dermatological indications, our product candidates FMX102 and FDX104 represent smaller opportunities and are not focused within the dermatological market, and therefore, are of lower priority in our R&D pipeline development.

We developed FMX101, FMX102, FMX103 and FDX104 using our proprietary technology, which includes our foam-based platforms. This technology enables us to formulate and stabilize a wide variety of drugs and deliver them directly to their target site. Our foam platforms have significant advantages over alternative delivery options and are suitable for multiple application sites, creating a potential pipeline of products across a range of conditions to drive future growth.

Parallel to our in-house developments, we have entered into development and license agreements relating to our technology with various pharmaceutical companies such as Bayer HealthCare AG (formerly, Intendis), Sebela

Pharmaceuticals Inc. (following the assignment to Sebela of our development and license agreement with Merz Pharmaceuticals, LLC in 2016), Mylan N.V. (following the acquisition of Renaissance Acquisition Holdings, LLC by Mylan in 2016) and Actavis Laboratories, a subsidiary of Teva Pharmaceutical Industries Ltd. Our total revenues from such agreements from our inception to December 31, 2016 were approximately $24.5 million.

In the third quarter of 2015, Bayer Healthcare began selling Finacea® Foam (azelaic acid) 15% for the treatment of rosacea in the U.S. Finacea is a prescription foam product which was developed as part of a research and development collaboration between Foamix and Bayer, utilizing Foamix's proprietary foam technology platform. According to our license agreement with Bayer, we are entitled to royalties and certain contingent payments upon commercialization of Finacea Foam, based on Bayer's net sales of Finacea. In 2016 we were entitled to $3.0 million from Bayer in royalties and $2.5 million in contingent payments related to the achievement of certain revenue targets, on account of its sales of Finacea.

Proprietary, innovative technology comprising different foam platforms

We have independently developed a series of proprietary foam platforms, each having unique pharmacological features and characteristics, which enable us to formulate, stabilize and deliver a wide variety of drugs directly to their target site. For example, minocycline is known to be very unstable and rapidly degrades in the presence of most commonly-used formulation components. Utilizing our proprietary technology, we successfully stabilized minocycline in a novel topical foam formulation. Our choice to develop foams over other platforms stems from foam's significant advantages over alternative delivery systems, being that it spreads easily and can be applied to large skin areas, is readily absorbed, avoids a messy residue and is highly tolerable due to its use of gentle ingredients. All ingredients used in our minocycline foam are listed in the FDA Inactive Ingredient Database, or IID, and are used in concentrations that do not exceed the maximum concentrations given in the IID. Our foam platforms are generally designed to be suitable for dermal, vaginal, nasal and other applications and to treat a range of diseases and disorders.

Product candidate pipeline

The following chart provides a summary of the developmental pipeline for our clinical-stage product candidates:

FMX101 for moderate-to-severe acne

Our lead product candidate, FMX101, minocycline foam 4%, is a novel topical foam formulation of minocycline for the treatment of moderate-to-severe acne.

Market opportunity

Acne is characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory lesions, papules and pustules and occasionally boils and scarring. It affects approximately 40 to 50 million people in the U.S. alone, of whom approximately 10 million suffer from moderate-to-severe acne. For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals continue to suffer from acne well into their 30s, 40s and later.

The market segment for aesthetic dermatology in general, and for indications such as acne in particular, is especially attractive because patients are highly motivated and more willing to pay out-of-pocket for treatments that will relieve them of the negative aesthetic aspects of the condition. As a result, we believe that patients will tolerate less favorable reimbursement schemes than they would when paying for drugs for other indications. We also believe FMX101 can expand the overall acne market by attracting new patients who currently avoid medication for their condition altogether, due to the unsatisfactory results of their previous treatment methods, and prefer a more tolerable treatment.

Limitations of oral minocycline for acne

Oral minocycline, such as Solodyn, is the current standard of care for moderate-to-severe acne. According to its product label, Solodyn did not demonstrate any effect on non-inflammatory acne lesions and reduced inflammatory lesions by 44% over the 12 week treatment period. According to its product label, the most common adverse systemic side effects of Solodyn include diarrhea, dizziness, drowsiness, indigestion, lightheadedness, loss of appetite, nausea, sore mouth, throat or tongue and vomiting.

In 2009, the FDA added oral minocycline to its Adverse Event Reporting System, a list of medications under investigation by the FDA, due to its severe side effects. In 2011, we conducted a blind survey of 40 U.S. dermatologists. The results of the survey revealed that 90% of the dermatologists surveyed who prescribed oral minocycline were concerned about its side effects, and 76% of these dermatologists stated they would prefer prescribing a topical minocycline drug over an existing oral medication, assuming the topical treatment was safe, effective and approved by the FDA.

FMX101 clinical results

We conducted a randomized, double-blind, dose-ranging, controlled Phase II clinical trial in Israel over 12 weeks with 150 patients between 12 and 25 years old with a mean age of approximately 16.5 years, each suffering from at least 20 inflammatory and 25 non-inflammatory facial lesions. The patients were randomly divided into three groups of 50 patients each, with one group receiving a 1% concentration of our minocycline foam, a second group receiving a 4% concentration and a third control group receiving our foam vehicle without minocycline, which we refer to as the vehicle. Each patient received one application daily before bedtime.

The primary efficacy endpoints of the trial were:

- the reduction in inflammatory and non-inflammatory lesions (as well as the total counts of facial lesions) over the course of the 12 week treatment;

- the investigator's global assessment, or IGA, based on the uniform graded scale adopted for the trial, ranging from "clear" skin with no inflammatory or non-inflammatory lesions, through "almost clear" skin, to "severe acne"; and

- safety and tolerability.

The trial was completed in 2013 and showed a dose-dependent effect that was statistically significant for both primary endpoints of the trial, namely reduction in inflammatory and non-inflammatory lesions and decrease of the IGA score. Notably, the effect on inflammatory lesions became statistically significant in the 4% dosage group versus the vehicle-only treatment group (placebo) after just three weeks of therapy, and the full therapeutic effect of approximately 71% reduction in inflammatory lesions was reached in the 4% dosage group after six weeks of treatment. Additionally, for the patients in the 4% dosage group, the effect on non-inflammatory lesions also became statistically significant versus the vehicle-only group after twelve weeks of therapy, with approximately a 73% reduction in non-inflammatory lesions.

The percent of patients with IGA improvement of at least two grades and a grading of clear or almost clear (score of 0 or1) at the completion of the trial was 20% in the 4% dosage group, compared with 4% in the 1% dosage group and 2% in the vehicle-only treatment.

The safety and tolerability profile of the drug was also favorable, with no serious adverse events and no reported drug-related systemic side effects. The cases of skin reaction in the trial were few, mild and transient, with all reactions subsiding by week 12 of treatment, and there was equal incidence of skin reaction in all three groups.

The following charts show the reduction of inflammatory from baseline and over the trial period for the 4% dosage, 1% dosage and vehicle treatment groups and the percentage of patients who met the IGA success criterion.

Additionally, in questionnaires filled out upon completion of the trial, 86% of the patients receiving the 4% dosage rated the drug as "very-highly" or "highly" effective compared to drugs they had formerly used, 98% of all patients were generally satisfied with the ease of use of the foam and 92% of all patients indicated they preferred the foam-based treatment over alternative topical products they had used in the past.

While we did not file a formal application for an IND with the FDA in connection with the FMX101 Phase II clinical trial, the trial was conducted in compliance with the International Conference of Harmonization, or ICH, good clinical practice, or GCP, guidelines and applicable Israel Ministry of Health regulations. The trial protocol complied with the procedures, criteria and endpoints specified by the FDA's 2005 draft industry guidance for acne trials. Because minocycline, the active ingredient in FMX101, is a well-known drug with an established safety profile, the ethical committee for our Phase II clinical trial and the Israeli Ministry of Health allowed us to conduct Phase II clinical trials of FMX101 without having first conducted a Phase I clinical trial.

We also completed a Phase I maximum use pharmacokinetics study of FMX101, intended to characterize the systemic absorption of minocycline after repeated maximum-dose applications in patients with moderate-to-severe acne, and to assess the relative bioavailability of topically-applied FMX101 compared to orally-administered Solodyn (minocycline HCl). The study enrolled 30 patients with moderate-to-severe acne on their face and on two or more other regions (neck, upper chest, upper back or arms) in a single-center, nonrandomized, open-label, active-controlled, two-period and two-treatment evaluation. Each of the patients received a single dose of Solodyn, 1 mg/kg in accordance with its approved instructions for use, and one week later received 4 grams of FMX101 applied topically once daily for 21 days. The study showed that the bioavailability, or systemic exposure, of minocycline following topical FMX101 administration was approximately 700 times lower than that of Solodyn, and that FMX101 was well tolerated with no serious adverse events being reported. We hope these results will provide a clinical bridge to the minocycline systemic safety data known to the FDA.

A series of Phase I human safety studies, were completed in 2016. Results of these trials to date are as expected and indicate no safety signals have been detected.

As part of our overall development plan for FMX101, we have conducted a series of animal safety studies, which revealed no signs of toxicity to date. We recently completed a long-term, 39-week dermal toxicity study in mini pigs, which included concentrations of our minocycline foam up to 16%. Initial results from this study also reflect no toxicity associated with our drug product. This study also is intended to support the NDA, as well as a long-term extension of the Phase III human studies, in which patients will be dosed for up to 12 months.

We also held an End of Phase II meeting with the FDA to review the clinical development plan for FMX101, and implemented the comments we received from the FDA regarding overall study design, primary efficacy endpoints, and safety assessments in the FMX101 Phase III program.

FMX101 Phase III clinical trials

Based on the results of the Phase II clinical trial, as described above, and guidance from the FDA in a pre-IND meeting, we initiated two multi-center pivotal Phase III clinical trials for FMX101 (minocycline foam 4%) in moderate-to severe acne, which are currently underway simultaneously in the U.S. In November 2016, we completed patient enrollment, with a total of 960 patients with moderate-to-severe acne enrolled between the two trials. Patients were randomized on a 2:1 basis (active compound vs. vehicle-only), initially into a 12-week double-blind phase where they are treated topically once daily with either FMX101 (minocycline foam 4%) or the respective foam vehicle. The two co-primary efficacy endpoints of both trials are: (1) the absolute change from baseline in inflammatory lesion counts in each treatment group at week 12; and (2) the proportion of patients achieving success at week 12 as defined by an IGA score of "clear" or "almost clear" and at least a two-grade improvement from baseline at week 12. Safety evaluation includes reported adverse events, assessments of tolerability, clinical laboratory tests and vital signs. Patients who complete the 12 week double-blind portion of the trials have the option to continue in a long-term open-label safety extension, aimed at evaluating the safety of intermittent use of FMX101 for up to nine additional months. We expect to report top-line results from the blinded phase of these Phase III clinical trials in the first half of 2017.

We expect to develop FMX101 through the FDA's 505(b)(2) regulatory pathway, which permits the filing of a new drug application, where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. This approach could expedite the development program for FMX101 by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. For additional information see "Risk Factors - If the FDA does not conclude that FMX101 or FMX103 satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or Section 505(b)(2), or if the requirements for this product candidate under Section 505(b)(2) are not as we expect, the approval pathway for this product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may

not be successful."

FMX103 for moderate -to-severe papulo-pustular rosacea

Our product candidate, FMX103, minocycline foam 1.5%, is a novel topical foam formulation of minocycline for the treatment of moderate-to-severe Papulopustular rosacea.

Market opportunity

Papulopustular rosacea is a chronic skin disease causing inflammatory lesions (papules and pustules) on the nose, cheeks, chin and forehead. It can create psychosocial burdens, such as embarrassment, anxiety and low self-esteem that adversely affect quality of life. Rosacea is most frequently seen in adults between 30 and 50 years of age and affects more than 16 million people in the U.S. alone. There is no known cure for rosacea and the exact root cause of the disease remains unknown as well, though both genetic and environmental factors are thought to have an impact on its outbreak. Mild papulopustular rosacea is treated by topical antimicrobials (such as metronidazole, clindamycin and ivermectin), or azelaic acid, while the mainstay for the treatment of moderate-to-severe rosacea are systemic antibiotics such as minocycline and doxycycline.

The current U.S. market size for rosacea is estimated to be approximately $1.2 billion, and we believe that our FMX103 product candidate for this indication, if approved, can offer a significant advantage over other currently available products.

FMX103 clinical results

In the third quarter of 2016, we announced positive top-line results from our Phase II trial evaluating FMX103. The double-blind, randomized, placebo-controlled Phase II trial was conducted in 18 sites in Germany and included 233 patients with moderate-to-severe rosacea. Patients were randomized to receive either one of two doses of FMX103 minocycline foam (3% or 1.5%) or vehicle foam once daily over 12 weeks, followed up by a four-week post-treatment evaluation. The efficacy endpoints were (i) the absolute change in the number of inflammatory lesions – papules and pustules (primary endpoint), and (ii) improvement of the IGA (first secondary endpoint). Safety and tolerability were also evaluated.

- Baseline severity. The mean baseline lesion count for all groups ranged from 30.6 to 34.5 and the IGA scores were all moderate (score 3) or severe (score 4); with about 50-60% of the subjects having a severe rating.

- Significant reduction in the number of inflammatory lesions. At the week 12 time point designated for the primary efficacy analysis, the 1.5% and 3% doses of FMX103 both significantly reduced the number of papules and pustules vs. the vehicle (1.5% and 3%, both p<0.001, , intent-to-treat analysis). The mean reduction in lesion count of each treatment group vs. its baseline was 21.1 for the 1.5% dose, 19.9 for the 3% dose and 7.8 for vehicle; the corresponding percent reductions were 61.4% and 55.5% for the FMX103 1.5% and 3% groups, respectively, and 29.7% for the vehicle.

- Significant improvement in Investigator's Global Assessment (IGA) scores. Both the 1.5% and 3% doses of FMX-103 were significantly better compared to vehicle alone in reducing the IGA score by two grades and in reaching a "clear" (score=0) or "almost clear" (score=1) rating at week 12 ($P < 0.01$ and $P < 0.05$, respectively. The percentage of subjects achieving at least a two grade point reduction and a rating of clear or almost clear (score of 0 or 1) was 25.3 for the 1.5% dose, 17.3 for the 3% dose, and 7.7 for vehicle. Both the 1.5% and 3% doses were efficacious and there was no statistically significant difference between these two doses.

- Safety and tolerability. FMX103 appeared to be generally safe and well-tolerated. There were no serious adverse events and no drug related systemic adverse events were reported. A few subjects overall exhibited treatment-related dermal adverse events (four and five in the 3% and vehicle groups, respectively and none in the 1.5% group). Four subjects discontinued the trial due to an adverse event (three in the 3% group and one in the vehicle group).

The following charts show the percentage reduction of inflammatory lesions from baseline and over the trial period for the 3% dose, 1.5% dose and vehicle-only treatment groups and the percentage of patients who met the IGA success criterion.

In December 2016, we conducted a pre-IND meeting with the FDA to confirm that our clinical and non-clinical programs outlined were sufficient to submit an IND and to begin our Phase III clinical trials. Utilizing the results of toxicology, pharmacology and human safety studies that were completed for FMX101, we now plan to conduct two independent Phase III clinical trials of FMX103, for moderate-to-severe papulo-pustular rosacea commencing during the first half of 2017. The Phase III clinical trials will be conducted primarily in the U.S. and will include two treatment groups, with one group receiving FMX103 in a 1.5% concentration and the other receiving the foam vehicle alone. The trials will be double-blinded and vehicle-controlled, and their protocols and endpoints will be conducted in accordance with the FDA's guidance, as provided in the pre-IND meeting.

FDX104 for chemotherapy-induced rash

FDX104 is a topical foam formulation of the antibiotic doxycycline for the treatment of severe acne-like rashes induced by chemotherapy.

Between 45% and 95% of patients taking epidermal growth-factor receptor inhibitors (EGRFI), such as cetuximab (Erbitux®, Eli Lilly), panitumumab (Vectibix®, Amgen) and erlotinib (Tarceva®, Genentech), are affected by these severe acne-like rashes, which typically occur in cosmetically sensitive areas such as the face and upper trunk. These symptoms can lead to patients modifying their dosage of EGFRI drugs and potentially stop treatment altogether. While there are no approved drugs for treatment of these rashes, oral doxycycline and minocycline are often used to treat these conditions, but they have significant shortcomings, including systemic side effects such as diarrhea, nausea and skin redness.

In the third quarter of 2015, we completed a Phase II clinical trial for FDX104 on patients with metastatic colon cancer who were treated with cetuximab or panitumumab. The results showed a statistically significant effect of FDX104 in reducing the severity of the rash.

Twenty-four patients were enrolled and received study drug in a multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the safety and efficacy of FDX104. Each patient acted as his or her own control by treating one side of the face with FDX104 and the other side with the matching foam vehicle (Placebo) in a blinded and randomized manner. Photographs of the face were taken at each study visit and were used for the grading of rash severity in a blinded manner by an independent dermatologist at the end of the study (General Rash Severity Score, GSS). Rash severity was also performed at each visit by the investigator (modified MASCC EGFR Inhibitor Papulopustular Eruption Grading Scale, MESTT). The GSS ratings of rash severity were: None = 0, Mild = 1, Moderate = 2 and Severe = 3. The key findings were:

- In the entire study population, (in all 24 patients in the study) the severity of rash on the FDX104 treatment side of the face was overall better than in the placebo-treated side.

- The mean maximal rash severity (in all 24 patients in the study) was 1.33 and 1.71 in the FDX104-treated and placebo-treated sides respectively.

- 9 of the 24 patients in the study (37.5%) developed severe (Grade 3) rash during the study on the placebo-treated side, while only 4 of the 24 patients in the study (16.7%) developed severe rash on the FDX104-treated side.

Comparison of the two treatments on the prevention of severe rash reached statistical significance ($p<0.05$, Wilcoxon Signed-Rank test. MESTT-based analyses had similar but non-statistically significant results. FDX104 was well-tolerated during the study. No drug-related systemic adverse events were recorded. Local reactions were noted in 6 patients, all were mild and 5 were resolved before the end of the study.

Based on the results of the FDX104 Phase II clinical trial, we are evaluating various clinical development options, as well as the potential market opportunity for this product.

FMX102 for impetigo

FMX102 is a formulation of our minocycline foam currently being developed for the treatment of impetigo.

We conducted a randomized, double-blind Phase II clinical trial in Israel over seven days with 32 pediatric patients ages two to 15 with at least two impetigo lesions. Of these patients, 32% were diagnosed with MRSA infection. The patients were randomly divided into two groups of 16 patients each, with one group receiving a 1% concentration of our minocycline foam and the other group receiving a 4% concentration of our minocycline foam, applied to each patient twice a day. No vehicle-only control was used, as ethical guidelines for pediatric trials in Israel do not permit the use of control groups.

The primary efficacy endpoints of the trial were (1) clinical success, defined as a total absence of treated lesions or certain specific improvements in the lesions during the trial and the continuous absence of the treated lesions or certain specific improvements in the lesions at follow-up; (2) bacteriological success, measured by elimination of the bacteria in the lesion as shown by a bacterial culture at end of treatment or follow-up or by the lack of any material to culture as a result of the lesion healing; and (3) safety and tolerability.

The trial was completed in 2012 and showed that approximately 80% of the patients in both groups met the clinical success criteria after three days of treatment. Clinical response at the end of the treatment (on day 7) was 92% for the 1% dosage and 100% for the 4% dosage, and all patients (100%) showed success by the fourteenth day of the trial. In a post-hoc analysis of the clinical trial results, eleven of the patients in this trial were also diagnosed with Methicillin-resistant Staphylococcus aureus (MRSA). Bacteriological success was reached in all 11 patients by the end of the trial and no presence of MRSA was detected. The safety and tolerability profile of the drug was favorable, and no drug-related side effects were reported during the trial.

In October 2015, we held a Pre-IND meeting with the FDA, to seek guidance with regards to the preclinical and clinical activities that are required to advance the development program of FMX102. The FDA requested that we conduct a photo-safety study prior to further evaluation of our clinical development plan. We began this photo-safety study in 2016, which remains ongoing. We are evaluating the clinical development plan and the business opportunity for this product.

Development roadmap and priorities

In view of the success of the Phase II trials for both FMX101 and FMX103, and the fact that these product candidates address widespread dermatological indications and significant market potential, we have decided to focus on these projects and invest the majority of our resources in FMX101 and FMX103. As a result, we will expand fewer resources on FMX102 and FDX104, which represent smaller opportunities and are not focused within the dermatological market.

Development and license agreements

Parallel to the development of our product candidates, we have entered into development and license agreements with various pharmaceutical companies, including such as Bayer HealthCare AG (formerly, Intendis), Sebela Pharmaceuticals Inc. (following the assignment to Sebela of our development and license agreement with Merz Pharmaceuticals, LLC in 2016), Mylan N.V. (following the acquisition of Renaissance Acquisition Holdings, LLC by Mylan in 2016) and Actavis Laboratories, a subsidiary of Teva Pharmaceutical Industries Ltd., combining our foam technology with drugs selected by the licensee to create new products with improved efficacy and ease-of-use. Each license agreement entitles us to service payments, contingent payments and royalties from sales of any new products that are commercialized. Each agreement is exclusive only to the specific drug that is licensed, leaving us the rights to commercialize and develop products with other drugs for the same indications using our proprietary foam technology while also allowing the licensee to apply the new products to any indication with its specific drug. The prospective products under these various agreements are currently in pre-clinical, Phase II, Phase III and commercial stages.

In September 2015, Bayer Healthcare began selling Finacea® Foam (azelaic acid) 15% in the U.S. Finacea Foam is a prescription topical drug which was developed by collaboration between Bayer and Foamix. It is the first prescription product developed using our proprietary technology that has been approved by the FDA for sale in the U.S. Bayer listed in the Orange Book several patents that were licensed from Foamix in connection with the development of Finacea Foam. According to our license agreement with Bayer, we are entitled to receive royalties and certain contingent payments upon the commercialization of Finacea Foam. In 2016 we were entitled to $3.0 million from Bayer in royalties and $2.5 million in contingent payments related to achievement of certain revenue targets, on account of its sales of Finacea.

Our total revenues from such agreements from our inception to December 31, 2016 were approximately $24.5 million.

Additional Research and Development

In addition to FMX101 for the treatment of moderate-to-severe acne, FMX103 for the treatment of moderate-to-severe rosacea, FMX102 for the treatment of impetigo and FDX104 for managing severe chemotherapy-induced rashes, and aside from the licensed products resulting from our development and license agreements with various pharmaceutical companies, we are developing a series of product candidates for a wide variety of indications to which we own worldwide rights and which are all based on formulations and adaptations of our patented, versatile foam platforms.

We intend to selectively proceed to clinical trials with these formulations under the FDA's 505(b)(2) regulatory pathway according to our identification of unmet needs and potential market opportunities.

Intellectual Property

Our intellectual property and proprietary technology are essential to the development, manufacture, and sale of FMX101, FMX102, FMX103 and FDX104 and our future pipeline products. We seek to protect our intellectual property, core technologies and other know-how, through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, licenses, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others. Additionally, we rely on our research and

development program, clinical trials, know-how and marketing and distribution programs to advance our products.

We submit applications directly or under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in any one of the designated member states. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

We also submit applications for a single European patent application covering member states. If granted, the European patent must be validated in each national member state in which the patent is to continue and becomes a bundle of individual national patents.

Our most important patents are several U.S. patents relating to our lead product candidates, FMX101, FMX102, FMX103 and FDX104, which are expected to remain in effect until 2030. These patents relate to a composition of matter comprising a claim to a formulation of a tetracycline antibiotic, which can include minocycline or doxycycline and therefore may be less protective than patents that claim a new drug. We also have patent applications claiming compositions of matter, which relate to FMX101, FMX102, FMX103 and FDX104, pending in each of the following international markets: Australia, Brazil, Canada, China, the European Union, India, Israel and Mexico.

Our other patents granted in the U.S. have claims relating to certain formulations of our foam platforms and other technology, including emulsion foams, hydrophobic foams, hydroalcoholic and aqueous foams.

As of December 31, 2016, we had a patent portfolio of 149 granted patents in certain countries worldwide, including 50 granted patents in the U.S. Additionally, as of December 31, 2016, we had over 80 pending patent applications worldwide, of which over 45 are pending in the U.S., describing and claiming our various foam based platforms and other technology. Our other pending applications relate to various foam platforms such as emulsion foam, hydrophobic foam, hydro-alcoholic foam and water-free foams, as well as specialty foams (such as potent solvent foams) and our recently-developed 'metered dose dispenser' for controllable dosing.

Competition

The medical and pharmaceutical industries in which we operate are intensely competitive and subject to significant technological change and changes in practice. While we believe that our innovative technology, knowledge, experience and resources provide us with competitive advantages, we may face competition from many different sources with respect to FMX101, FMX103 and our other pipeline products or any product candidates that we may seek to develop or commercialize in the future. Possible competitors may include pharmaceutical companies, academic and medical institutions, governmental agencies and public and private research institutions. These prospective competitors have the ability to effectively discover, develop, test and obtain regulatory approvals for products that compete with ours, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff.

At the end of 2014 we became aware that an active pharmaceutical ingredient and drug product intermediate manufacturer, Hovione, had submitted an IND for Phase I and II clinical trials of a new topical gel suspension containing minocycline for the treatment of inflammatory skin disease, including acne and rosacea. Hovione is a privately-held company and we do not know if they have commenced a clinical trial for such a new topical minocycline product. During 2015 we became aware that another company, BioPharmX Corporation (NYSE MKT: BPMX), is developing a topical hydrophilic gel containing minocycline for treatment of acne, known as BPX-01, for which BioPharmX has announced Phase IIa clinical trial results. If ultimately approved and launched in the US, these products would become direct competitors to FMX101 and FMX103, if commercialized.

Further, we are developing certain topical products with several licensees combining our proprietary technology with a drug selected by the licensee. While the licenses we grant are exclusive with respect to the specific drug which is licensed, our agreements with these licensees allow them to commercialize the licensed developed products for any topical dermatological application, not just for the specific indication for which each product was originally intended. If any such licensed product proves to be effective for moderate-to severe acne, impetigo, rosacea, chemotherapy-induced rash, or any other indication that we are pursuing with FMX101, FMX103 or our other product candidates, we may face competition from these licensees, as they are not bound by non-compete restrictions. Although we believe that FMX101, FMX103 and our other product candidates can outperform the licensed products in the specific indications our product candidates are targeting, such licensed products may nevertheless pose a competitive challenge, as they will have the benefit of our foam technology coupled with the licensees' greater resources, experience and brand recognition, extensive marketing channels and other capabilities, and possibly the advantage of entering the market before us.

In addition to products that are currently available, other products may be introduced to treat acne, rosacea, impetigo and other skin disorders during the time that we engage in necessary development. Accordingly, if one of our pipeline products is approved, our main challenge in the market would be to convince dermatologists, pediatricians or other physicians seeking alternatives to oral or other existing treatments to use our product instead. While we are still in the preliminary stages, based on our studies, we believe that our pipeline products could be more effective than the current non-topical alternatives and exhibit significantly less adverse side effects.

Government Regulation

Our business is subject to extensive government regulation. Regulation by governmental authorities in the U.S. and other jurisdictions is a significant factor in the development, manufacture and marketing of our foam delivered treatments and in our ongoing research and development activities.

Product approval process in the U.S.

Review and Approval of Drugs

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations and other laws, including the Public Health Service Act. Drugs require the submission of a new drug application, or NDA, and approval by the FDA prior to being marketed in the U.S. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions and enforcement actions brought by the FDA, the Department of Justice or other governmental entities. Possible sanctions may include the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

The process required by the FDA prior to marketing and distributing a drug in the U.S. generally involves the following:

- completion of laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, or other applicable regulations;
- submission to the FDA of an application for an IND designation, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation and submission to the FDA of an NDA or supplemental NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product or components thereof are produced, to assess compliance with current good manufacturing processes, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- payment of user fees and FDA review and approval of the NDA.

Preclinical studies

Preclinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests must be conducted in compliance with the FDA's GLP regulations. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before clinical trials may be commenced.

Clinical trials in support of an NDA

Clinical trials involve the administration of an investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase I: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase II: The drug is administered to a limited patient population to identify possible short-term adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase III: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Submission of an NDA to the FDA

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture, control and composition of the product, are submitted to the FDA as part of an NDA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, applicants are required to pay fees to the FDA for reviewing an NDA. These user fees, as well as the annual fees required for commercial manufacturing establishments and for approved products, can be substantial. The NDA review fee alone can exceed $2.3 million, subject to certain limited deferrals, waivers and reductions that may be available. Each NDA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If found complete, the FDA will "file" the NDA, thus triggering a full review of the application. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission.

The FDA's established goal is to review 90% of NDA applications and original efficacy supplements given 'Priority' status within 6 months, and 90% of applications and original efficacy supplements given 'Standard' status within 10 months, whereupon a review decision is to be made. The FDA, however, may not approve a drug within these established goals, and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but rather an "action letter" that describes additional work that must be completed before the application can be approved.

Before approving an NDA, the FDA inspects the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process, and will not approve the product unless cGMP compliance is satisfactory. The FDA may deny approval of an NDA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or may never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies or trials be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or impose other limitations.

Once a product is approved, marketing the product for other indicated uses or making certain manufacturing or other changes requires FDA review and approval of a supplement NDA or a new NDA, which may require additional clinical data and review fees. In addition, further post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidate under development.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies or trials not conducted by or for the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference, or "listed" drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies that are listed in the FDA's Publication of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the 'Orange Book'. Specifically, the applicant must certify for each listed patent that, in relevant part, (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product.

A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay.

Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year exclusivity period and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation.

In addition to patent protections applicable to a listed drug, a Section 505(b)(2) application may be subject to periods of statutory market exclusivity afforded to an approved new drug. Statutory market exclusivity provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug product, and precludes approval of certain 505(b)(2) applications for prescribed periods of time. Exclusivity is available for new chemical entities, as well as for significant changes in already approved drug products, such as a new use. FDA may refuse to approve a Section 505(b)(2) application to the extent it is subject to the market exclusivity.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Post-approval requirements

Any drug products for which we receive FDA approval will be subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or patient populations that are not described in the drug's approved labeling, known as "off-label use," and other promotional activities, such as those considered to be false or misleading. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses. As a result, "off-label promotion" has formed the basis for litigation under the Federal False Claims Act, violations of which are subject to significant civil fines and penalties. In addition, manufacturers of prescription products are required to disclose annually to the Center for Medicaid and Medicare any payments made to physicians and teaching hospitals in the U.S. under the federal Physician Payment Sunshine Act.

Reportable payments may be direct or indirect, in cash or kind, for any reason, and are required to be disclosed even if the payments are not related to the approved product. Failure to fully disclose or not in time reporting could lead to penalties up to $1.15 million per year.

The manufacturing of any of our products will be required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. The FDA's cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved NDA, as well as lead to potential market disruptions. These restrictions may include recalls, suspension of a product until the FDA is assured that quality standards can be met, and continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, or Phase IV testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of our products.

Pediatric trials and exclusivity

Even when not pursuing a pediatric indication, under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, in 2012, sponsors must also submit pediatric trial plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric trials the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA.

Separately, in the event the FDA makes a written request for pediatric data relating to a drug product, an NDA sponsor who submits such data may be entitled to pediatric exclusivity. Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional 6 months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity.

Patent term restoration and extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically 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 a NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. Since the active pharmaceutical ingredients of FMX101, FMX102, FMX103 and FDX104 are already known and marketed in tablet form, these products may not be eligible for the said patent term extension, if applicable.

Orphan drug designation

Orphan drug designation in the U.S. is designed to encourage sponsors to develop drugs intended for rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the U.S.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the drug's marketing approval, if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A drug becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development, or OOPD, at the FDA based on acceptable confidential requests made under the regulatory provisions. The drug must then go through the new drug approval process like any other drug. Orphan drug designations are decided solely by the OOPD staff, but the OOPD occasionally will request opinions from the Center for Drug Evaluation and Research, especially when dealing with issues such as the appropriateness of the requested indication or the scientific rationale described by the sponsor.

A sponsor may request orphan drug designation of a previously unapproved drug or new orphan indication for an already marketed drug. In addition, a sponsor of a drug that is otherwise the same drug as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent drug for the same rare disease or condition if it can present a plausible hypothesis that its drug may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same drug for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the drug has been designated. The FDA could approve a second application for the same drug for a different use or a second application for a clinically superior version of the drug for the same use. The FDA cannot, however, approve the same drug made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Review and approval of drug products outside the U.S.

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized, decentralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure includes selecting one "reference member state," or RMS, and submitting to more than one member state at the same time. The RMS National Competent Authority conducts a detailed review and prepares an assessment report, to which concerned member states provide comment. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states post-initial approval. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize the approval.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and other markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers. Third-party payers include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of FMX101, in addition to the costs required to obtain the FDA approvals. Additionally, FMX101 may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In March 2010, the President of the U.S. signed one of the most significant healthcare reform measures in decades. The healthcare reform law substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The comprehensive $940 billion dollar overhaul is expected to extend coverage to approximately 36 million previously uninsured Americans. The healthcare reform law contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the

physician quality reporting system and feedback program.

Additionally, the healthcare reform law:

- increases the minimum level of rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs

There have been proposed in Congress a number of legislative initiatives regarding healthcare, including possible repeal of the healthcare reform law. At this time, it remains unclear whether there will be any changes made to the healthcare reform law, whether to certain provisions or its entirety.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies or trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare laws and regulations

Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, third-party payers and other customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also 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.

Manufacturing, Supply and Production

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, active ingredients and finished products for our preclinical research and clinical trials, including the Phase III clinical trials for FMX101, FMX103 and our additional product candidates, as applicable. We have contractual relationships for the manufacture of clinical supplies of FMX101 and FMX103, and for commercial supplies if these products are approved. If FMX101, FMX103 or any of our other product candidates are approved by any regulatory agency, we intend to enter into additional agreements with one or more third-party contract manufacturers as secondary manufacturers for the commercial production of these products. We, and our contract manufacturers, are developing the validation processes, methods, tests and or controls suitable for commercial scale manufacturing of our various product candidates and for defining their properties. Changes in manufacturing scale or the manufacturer may require changes to processes, methods, tests and or controls, which may take time to develop, validate and implement.

Development stage 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 and external resources to manage our manufacturing contractors. The relevant manufacturers of our drug products for our current preclinical and clinical trials have advised us that they are compliant with both Good Laboratory Practices, or GLP, and current Good Manufacturing Practices, or cGMP.

Our product candidates, if approved, may not be producible in sufficient commercial quantities, in compliance with regulatory requirements or 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 foreign regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

We use, and we intend to continue to use, leading providers of manufacturing services to the global pharmaceutical industry, to scale-up and validate a robust manufacturing process to support commercialization and distribution of our products if approved by the FDA.

Marketing, Sales and Distribution

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure. Extensive planning and market research has been conducted on our current product portfolio. Additionally, continuous efforts are deployed to identify unmet needs in the dermatology market, asses their commercial potential and advise on the prioritization of the development of our future product candidates accordingly. We have formed a U.S. subsidiary, Foamix Pharmaceuticals Inc., with five key executives to support our clinical development, regulatory affairs, CMC / drug development, and commercialization efforts in the U.S.

We are also evaluating the optimal price range for FMX101 and FMX103, that will reflect their benefits relative to alternative treatments while remaining affordable to potential customers and reimbursable by governments and third-party payers.

In the event that we receive regulatory approvals for FMX101 and FMX103 in markets outside of the U.S., 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 or sell our products through their well-developed sales, marketing and distribution organizations in such countries.

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.

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily Israel, governing, among other things, (i) the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; and (ii) chemical, air, water and ground contamination, air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations at our Rehovot research and development facility use chemicals and produce waste materials and sewage. Our activities require permits from various governmental authorities including, local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted. For instance, Israeli regulations were promulgated in 2011 relating to the discharge of industrial sewage into the sewer system. These regulations establish new and potentially significant fines for discharging forbidden or irregular sewage into the sewage system.

The operations of our subcontractors and suppliers are also subject to various Israeli and foreign laws and regulations relating to environmental, health and safety matters, and their failure to comply with such laws and regulations could have a material adverse effect on our business and reputation, result in an interruption or delay in the development or manufacture of our product candidates, or increase the costs for the development or manufacture of our product candidates.

Legal Proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings. We may become involved in material legal proceedings in the future.

4.C. Organizational structure

We were formed as a company in the State of Israel on January 19, 2003.

Our corporate structure consists of Foamix Pharmaceuticals Ltd. and Foamix Pharmaceuticals Inc., our wholly-owned U.S. subsidiary, which was incorporated on May 6, 2014, under the laws of the State of Delaware, and which is intended to serve as our marketing and sales arm in the U.S.

4.D. Property, plants and equipment

Our facilities in Israel, which house our headquarters and our research and developments laboratories, are located at two sites in the Weizmann Science Park in Rehovot, Israel. Under a Lease Agreement with Gav Yam Lands Ltd., we are leasing approximately 2,199 square meters until December 31, 2020. Under a Lease Agreement with Shrada Ltd. we are leasing approximately 550 square meters until February 28, 2017. Our executive offices in the U.S. are located in Bridgewater, New Jersey. The lease agreement was signed in September 2014, expires on August 31, 2017 and consists of approximately 770 square meters of space. We believe that our current office space in Israel is sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business. We may need to secure larger office space to support the internal growth of our U.S. organization.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

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.A. 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 annual report, particularly in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

5.A. Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2016, 2015 and 2014:

	Year ended December 31,		
	2016	2015	2014
	(in thousands of US$)		
Revenues	$5,527	$849	$5,414
Cost of revenues[(1)]	59	70	527
Gross profit	5,468	779	4,887
Operating expenses			
Research and development[(1)]	25,897	10,680	3,557
Selling, general and administrative[(1)]	9,221	7,029	2,964
Total operating expenses	35,118	17,709	6,521
Operating loss	29,650	16,930	1,634
Finance expenses (income), net	(701)	(452)	9,844
Income tax	387	39	6
Net loss	$29,336	$16,517	$11,484

(1) Includes share-based compensation expenses as follows:

	Year ended December 31,		
	2016	2015	2014
	(in thousands of US$)		
Cost of revenues	$ 3	$ 2	$ 15
Research and development	1,135	588	80
Selling, general and administrative	1,774	1,187	102
Total share-based compensation	$ 2,912	$ 1,777	$ 197

Revenues

To date, we have not generated any revenues from sales of FMX101 or any of our other product candidates. We do not expect to commercially launch FMX101 or other product candidates or generate any revenues from sales of any of our product candidates before 2018, after completing their development and clinical testing and obtaining approvals for their marketing in the U.S. Our ability to generate revenues from sales will depend on the successful commercialization of FMX101 and our other product candidates.

As of December 31, 2016, we had generated cumulative revenues of approximately $24.5 million under development and license agreements, of which approximately $18.2 million were development service payments, approximately $3.1 million were contingent payments and $3.2 million were royalty payments. Our total revenues for the years

ended December 31, 2016, 2015 and 2014 were $5.5 million, $849,000 and $5.4 million, respectively. We may become entitled to additional contingent payments, subject to achievement of the applicable clinical results by our licensees. In light of the current phase of development under these agreements, we do not expect to receive significant payments in the near term, if at all. We are also entitled to additional royalties from net sales or net profits generated by other products to be developed under these agreements, if they are successfully commercialized. In those development and license agreements in which royalties are based on net sales, their rate ranges from 3% to 8.5%, and in the agreement in which royalties are based on net profits, their rate is 6%.

Pursuant to a collaboration agreement with Bayer HealthCare AG, we are entitled to receive royalty payments with respect to Finacea®, a prescription foam product that we developed in collaboration with Bayer. As of December 31, 2016, we were entitled to receive royalty payments in an amount of $3.2 million, and an additional contingent payment in the amount of $2.5 million for the achievement of certain revenue targets.

Cost of revenues

Cost of revenues includes costs and expenses we incur in supplying services to our licensees under our development and license agreements with them. These services include design and development of product prototypes, performance of in-vitro studies and other lab tests, compiling project reports and recommendations and carrying out other tasks related to such efforts. Our services to licensees do not include development work beyond the prototype stage, clinical trials or pursuit of regulatory approval, which are the responsibility and at the expense of each licensee.

Accordingly, our cost of revenues includes payroll and other payments on behalf of the employees and consultants assigned to these projects; laboratory services related to the studies we perform on behalf of the licensees; rent and office maintenance costs related to the use of our facilities and infrastructure, utilities and other overhead services in connection with the projects performed for the licensees.

Our total cost of revenues for the twelve months ended December 31, 2016, 2015 and 2014 were $59,000, $70,000 and $527,000, respectively. We do not expect substantial changes in cost of revenue unless and until we obtain regulatory approval for our lead product candidates and begin serial production of such products, whether internally or through third party manufacturers, at which point we expect our cost of revenues to grow along with the growth of our sales and inventory needs.

Cost of revenues as a percentage of revenues for the twelve months ended December 31, 2016, 2015 and 2014 were 1.1%, 8.2%, and 9.7%, respectively. The decrease in cost of revenues is primarily due to the decrease in new development projects and the increase in royalty and contingent payments which do not bear related cost of revenue.

Operating Expenses

Research and development expenses

Research and development activities are, and will continue to be, central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our pipeline products progress into clinical trials. However, we do not believe that it is possible at this time to accurately project total program-specific expenses to reach commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will affect our clinical development programs and plans.

Our research and development expenses relate primarily to the development of FMX101. From 2007 until December 31, 2016, we cumulatively spent approximately $47.1 million on research and development of FMX101 and our other product candidates. Our total research and development expenses for the years ended December 31, 2016, 2015 and 2014 were approximately $25.9, $10.7 and $3.6 million, respectively. We charge all research and development expenses to operations as they are incurred. We expect research and development expenses to increase in the near term due to the ongoing and beginning of Phase III clinical trials for FMX101 and FMX103.

The successful development of FMX101, FMX103 and additional product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our technology for additional indications. This uncertainty is due to numerous risks and variables associated with developing products, including the uncertainty of:

·the scope, rate of progress and expense of our research and development activities;

- preclinical results;
- clinical trial results;
- the terms and timing of regulatory approvals;
- our ability to file, prosecute, obtain, maintain, defend and enforce patents and other intellectual property rights and the expense of filing, prosecuting, obtaining, maintaining, defending and enforcing patents and other intellectual property rights;
- the ability to market, commercialize and achieve market acceptance for FMX101 or any other product candidate that we may develop in the future; and
- our ability to identify, evaluate, acquire or in-license intellectual property, if needed, to facilitate the commercialization of our products and technologies.

A change in the outcome of any of these variables with respect to the development of FMX101, FMX103 or our other product candidates could result in a significant change in the costs and timing associated with their development. For example, if the FDA or foreign regulatory authority were to require us to conduct preclinical studies and clinical trials beyond those which we currently anticipate for the completion of clinical development of our product candidates, or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

Research and development expenses consist primarily of:

- employee-related expenses, including salaries, benefits and related expenses, including share based compensation expenses;
- expenses incurred under agreements with third parties, including subcontractors, suppliers and consultants that conduct regulatory activities, clinical trials and preclinical studies;
- expenses incurred to acquire, develop and manufacture clinical trial materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs; and
- costs associated with preclinical and clinical activities and regulatory operations.

We have managed to finance our research and development operations and expenses without the aid of government grants, other than a loan in the amount of approximately $450,000 received from the Israel-U.S. Bi-national Industrial Research and Development Foundation, or BIRD, in 2008. Accordingly, we are not subject to the provisions of the Law for Encouragement of Research and Development in Industry, 5744-1984, nor to any directives issued by the Israeli Office of the Chief Scientist.

Selling, general and administrative expenses

Our selling, general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and related expenses, including share based compensation expenses;
- costs associated with market research and business development activities in preparation for future marketing and sales, including activities intended to select the most promising product candidates for further development and commercialization;
- legal and professional fees for auditors and other consulting expenses not related to research and development activities or to market research or business development activities;
- cost of offices, communication and office expenses;
- information technology expenses;
- depreciation of tangible fixed assets related to our general and administrative activities or to our market research and business development activities; and
- costs associated with filing, prosecuting, obtaining and maintaining patents and other intellectual property.

As part of our growth strategy, we have begun building up our dedicated U.S. marketing and business development team and infrastructure, and we intend to further increase such U.S. infrastructure, as well as expand our marketing effort to new markets. We therefore expect selling and marketing expenses to increase in absolute terms as a percentage of our revenues. Our total selling, general and administrative expenses for the years ended December 31, 2016, 2015 and 2014 were approximately $9.2, $7.0 and $3.0 million, respectively.

Financial income

Financial income consists primarily of gains from interest earned from our bank deposits and financial income on our marketable securities.

Taxes on income

During 2014 and 2015 the standard corporate tax rate in Israel was 26.5%, and during 2016 it was 25%.

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately $50.1 million as of December 31, 2016. We anticipate that we will be able to carry forward these tax losses to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

During 2016, 2015 and 2014 we incurred tax expenses of $387,000, $39,000 and $6,000, respectively, in our US subsidiary, Foamix Pharmaceuticals Inc.

Comparison of the Year ended December 31, 2016 to the Year Ended December 31, 2015

Revenues

Our total revenues increased by $4.7 million, or 553%, from $849,000 in the year ended December 31, 2015 to $5.5 million in the year ended December 31, 2016. The increase is mainly due to the increase of $2.7 million in royalty payments from Bayer HealthCare AG for the sales of Finacea® Foam, and additional contingent payments totaling $2.5 million, due to Bayer's achievement of certain sale targets during 2016.

Cost of revenues

Our cost of revenues for the years ended December 31, 2016 and 2015 were $59,000 and $70,000, respectively. The $11,000 decrease in cost of revenues resulted primarily from a decrease in the development projects. Cost of revenues as a percentage of revenues for the years ended December 31, 2016 and 2015 was 1.1% and 8.2%, respectively. The decrease in the cost of revenues as a percentage of revenues was primarily due to the increase in royalty and contingent payments, to which no cost of revenue is related.

Research and development expenses

Our research and development expenses for the year ended December 31, 2016 were $25.9 million, representing an increase of $15.2 million, or 142%, compared to $10.7 million for the year ended December 31, 2015. The increase in research and development expenses resulted primarily from an increase of $12.8 million in costs relating to the FMX101 and FMX103 clinical trials and an increase of $2.2 million in payroll and payroll related expenses due to an increase in the number of R&D employees.

Selling, general and administrative expenses

Our general and administrative expenses for the year ended December 31, 2016 were $9.2 million, representing an increase of $2.2 million, or 31%, compared to $7.0 million for the year ended December 31, 2015. The increase in selling, general and administrative expenses resulted primarily from an increase of $1.3 million in payroll and other payroll-related expenses mainly due to an increase in headcount; an increase of $417,000 in market research expenses; an increase of $225,000 in travel expenses; and an increase of $201,000 in expenses related to the Company's board of directors.

Operating loss

As a result of the foregoing, our operating loss for the year ended December 31, 2016, was $29.6 million, compared to an operating loss of $16.9 million for the year ended December 31, 2015, an increase of $12.7 million, or 75%.

Finance income

In the year ended December 31, 2016, our financial income included mostly gains from marketable securities and interest earned on our bank deposits, partially offset by expenses on the loan from the BIRD foundation fully repaid during the second quarter of 2016. In the year ended December 31, 2015 our financial income included mostly gains from marketable securities and interest earned on our bank deposits.

The finance expenses (income) by cash and non-cash components are as follows:

	Year ended December 31,	
	2016	2015
	(in thousands of US$)	

Other expenses	$ 17	$ 23
Finance expenses on BIRD loan	243	*
Total expenses	260	23
Less:		
Interest on bank deposits	(536)	(289)
Gain from marketable securities, net	(401)	(180)
Non-cash foreign exchange profit, net	(24)	(6)
Total income	(961)	(475)
Finance income, net	$ (701)	$ (452)

* Less than $1,000

Taxes on income

During 2015 and 2016, we have not generated taxable income in Israel. However, we had incurred tax expenses in our US subsidiary, Foamix Pharmaceuticals, Inc, in the amount of $39,000 and $387,000 for the years 2015 and 2016 respectively.

Net Loss

As a result of the foregoing our loss for the year ended December 31, 2016 was $29.3 million, compared to $16.5 million for the year ended December 31, 2015, an increase of $12.8 million, or 78%.

Comparison of the Year ended December 31, 2015 to the Year Ended December 31, 2014

Revenues

Our total revenues decreased by $4.6 million, or 84.3%, from $5.4 million in the year ended December 31, 2014, to $849,000 in the year ended December 31, 2015, due to completion of certain development projects for our licensees that generated development fees during 2014, and resulted in products that had begun clinical trial phases or commercialization at the end of 2015, and thus did not generate substantial fees during that year.

Cost of revenues

Our cost of revenues for each of the years ended December 31, 2015 and 2014 consisted of the following items:

	Year ended December 31,	
	2015	2014
Cost of revenues	(in thousands of US$)	
Payroll and related expenses	$ 27	$ 385
Testing, professional and laboratory services	4	72
Rent and office maintenance	31	37
Other	8	33
Total	$ 70	$ 527

Our cost of revenues for the years ended December 31, 2015 and 2014 were $70,000 and $527,000, respectively. The $457,000 decrease in cost of revenues resulted primarily from a decrease in the development projects. Cost of revenues as a percentage of revenues for the years ended December 31, 2015 and 2014 were 8.2% and 9.7%, respectively. The decrease in cost of revenues as a percentage of revenues resulted primarily from the fact that royalty payments received in 2015 had no cost related to them.

Research and development expenses

Our research and development expenses for the year ended December 31, 2015 were $10.7 million, representing an increase of $7.1 million, or 100%, compared to $3.6 million for the year ended December 31, 2014. The increase is primarily due to an increase of $4.0 million in costs relating to the preparation and ongoing FMX101 and FMX103 clinical trials and expenses with respect to the FDX104 clinical trial, an increase of $649,000 in advisory and consulting expenses and an increase of $2.3 million in payroll and related expenses due to an increase in the number of R&D employees.

Selling, general and administrative expenses

Our general and administrative expenses totaled $7.0 million for the year ended December 31, 2015, an increase of $4.1 million, or 37.1%, compared to $3.0 million for the year ended December 31, 2014. The increase resulted primarily from an increase of $2.2 million in payroll and related expenses, an increase of $196,000 in investor relations expenses, an increase of $529,000 in expenses related to directors' compensation, an increase of $255,000 in rent and office maintenance and an increase of $195,000 in expenses related to advisors and other professional fees.

Operating loss

As a result of the foregoing, our operating loss for the year ended December 31, 2015 was $16.9 million, as compared to an operating loss of $1.6 million for the year ended December 31, 2014, an increase of $15.3 million, or 836%.

Finance expenses

Finance expenses, net, includes cash and non-cash components. The cash component of finance expenses, net, consists of bank fees and realized gain or loss on marketable securities. The non-cash components of our finance expenses, net, consist of (i) finance expenses on convertible loans and warrants, (ii) linkage of the BIRD foundation loan to the U.S. CPI, and (iii) gain or loss from foreign currency exchange differentials. Our finance expenses by cash and non-cash components are as follows:

	Year ended December 31,	
	2015	2014
	(in thousands of US$)	
Non-cash—finance expenses on convertible loans and warrants	$ -	$ 9,915
Other expenses	23	15
Total expenses	23	9,930
Less:		
Interest on bank deposits	(289)	-
Gain from sale of marketable securities	(180)	(11)
Other income	-	(28)
Non-cash foreign exchange profit, net	(6)	(47)
Finance expenses, net	$ (452)	$ 9,844

Finance expenses, net, decreased by $10.3 million, or 104.6%, from $9.8 million in the year ended December 31, 2014, to $(452,000) (meaning a positive financial income of $452,000) in the year ended December 31, 2015. The decrease was primarily due to the fact that in 2014 we had significant non-cash finance expenses on convertible loans and warrants, that were converted into shares during that year and were no longer outstanding in 2015, while in 2015 we had financial income from investment securities and interest earned on our bank deposits following our initial public offering in the third quarter of 2014.

Taxes on income

During 2014 and 2015, we have not generated taxable income in Israel. However, during 2014 we incurred a tax expense in the amount of $6,000 in our US subsidiary, Foamix Pharmaceuticals, Inc., and in 2015 we incurred a tax expense of $39,000. We do not foresee any material tax liabilities, in Israel or the US, in the near future.

Net Loss

As a result of the foregoing, our loss for the year ended December 31, 2015 was $16.5 million, compared to $11.5 million for the year ended December 31, 2014, an increase of $5.0 million, or 43.8%. The increase in net loss is due primarily to the decrease in our revenues in 2015, which was compounded by the increase in our research and development expenses and selling, general and administrative expenses and partially offset by a decrease in our net finance expenses in such year compared to 2014, as described above.

For information regarding the impact of foreign currency fluctuations on the company see "Item 11 – Quantitative and Qualitative Disclosures About Market Risk — Foreign Currency Exchange Risk."

5.B. Liquidity and capital resources

Liquidity

Since our inception, we have incurred losses from operations and negative cash flows from our operations. For the twelve months ended December 31, 2016, we incurred a net loss of $29.3 million, which included $27.4 million used for operating activity. For the year ended December 31, 2015 we incurred a net loss of $16.5 million, which included $12.5 million used for operating activity. As of December 31, 2016 and December 31, 2015, we had a working capital surplus of $111.7 million and $53.1 million, respectively, and an accumulated deficit of $75.6 million and $46.2 million, respectively. Our principal source of liquidity as of December 31, 2016 consisted of cash, cash equivalents, restricted cash, bank deposits and marketable securities of $131.0 million.

In the second quarter of 2014, we completed a private placement of preferred A shares and warrants with a group of new investors and several of our existing shareholders in two phases, on May 13, 2014 and June 3, 2014, raising a total of $8.2 million, net of issuance costs, in consideration of 1,036,431 preferred shares and 1,061,469 warrants to purchase preferred shares.

In September 2014, we completed our initial public offering in which we sold 6,700,000 ordinary shares for $6.00 per share raising total net proceeds, after expenses, of approximately $35.7 million. In October 2014 the underwriters exercised their option to purchase an additional 968,200 ordinary shares at a price of $6.00 per share. The proceeds from the exercise of the option, net of underwriters' commission, were approximately $5.4 million, bringing the total net proceeds from the initial public offering, after expenses, to approximately $41.1 million.

In April 2015, we completed a follow-on offering in which we sold 7,419,353 ordinary shares, including the exercise of underwrites option, for $9.30 per share, raising total net proceeds, after expenses, of approximately $64.2 million.

On October 21, 2015, we filed with the Securities and Exchange Commission (the SEC) a "shelf" registration statement on a Form F-3 for the registration of our ordinary shares that we may, from time to time, offer and sell in one or more offerings with an aggregate offering price of up to $150 million. On September 12, 2016 we filed with the SEC an amendment to the shelf registration statement on a Form F-3/A, which became effective on September 23, 2016.

On September 30, 2016, we completed another follow-on offering under our amended shelf registration statement, in which we sold 5,700,000 ordinary shares for $9.50 per share, raising net proceeds, after expenses and underwriter commissions, of approximately $50.4 million. An additional 300,000 ordinary shares were sold by certain selling shareholders. In October 2016 the underwriters partially exercised the option granted to them in the underwriting agreement and purchased an additional 411,959 ordinary shares at a price of $9.50 per share. The proceeds from the exercise of the option, net of expenses and underwriter commissions, were approximately $3.7 million, bringing the total net proceeds from the offering to approximately $54.1 million.

We anticipate that we will be able to fund our operating expenses and capital expenditure requirements throughout the Phase III clinical trials and NDA filings for our lead product candidates, FMX101 and FMX103, which we expect to complete by 2018 and 2019, respectively.

Foamix Pharmaceuticals Inc., our wholly-owned subsidiary, was incorporated on May 6, 2014 under the laws of the State of Delaware, with the intent to serve as our marketing and sales arm in the U.S. As a result, we do not expect our subsidiary to distribute any dividends, or extend any loans or advances to us in the foreseeable future.

Capital resources

Overview

To date, we have financed our operations through private and public placements of our ordinary shares, convertible loans and through fees, cost reimbursements and royalties received from our licensees.

From inception through December 31, 2016, we have received net cash proceeds of approximately $187.6 million from the sale of ordinary shares, preferred shares, exercise of options and warrants and from convertible loans.

Cash flows

The following table summarizes our statement of cash flows for the years ended December 31, 2016, December 31, 2015 and December 31, 2014:

	Year ended December 31,		
	2016	2015	2014
	(in thousands of US$)		
Net cash used in:			
Operating activities	$(27,370)	$(12,498)	$(714)
Investing activities	(15,018)	(78,516)	(7,349)
Financing activities	$55,031	$66,801	$49,339

Net cash used in operating activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net income for non-cash items mainly include depreciation and amortization, finance expenses on convertible loans and warrants and share-based compensation.

Net cash used in operating activities was $27.4 million in the twelve months ended December 31, 2016, compared to $12.5 of net cash used in operating activities in the twelve months ended December 31, 2015 and compared to $714,000 of net cash used in operating activities in the twelve months ended December 31, 2014. The increase was attributable primarily to the increase in company activity mostly related to clinical trials and payroll expenses.

Net cash used in investing activities

The use of cash in investing activities has been primarily related to purchase of marketable securities and investment in bank deposits. Net cash used in investing activities was $15.0 million in the twelve months ended December 31, 2016, compared to $78.5 million in the twelve months ended December 31, 2015 and compared to $7.3 million in the twelve months ended December 31, 2014. The decrease in investing activities between 2016 and 2015, was attributable primarily to increase in proceeds from sale and maturity of marketable securities and bank deposits, and the decrease in cash invested compared to 2015. The increase in investing activities between 2015 and 2014, was attributable primarily to investment of the cash raised in our 2015 follow-on offering, in bank deposits and marketable

securities.

Net cash provided by financing activities

Net cash provided by financing activities was $55.0 million in the twelve months ended December 31, 2016, a decrease of $11.8 million from $66.8 million in the twelve months ended December 31, 2015. The decrease was attributable primarily to a larger amount of capital raised in the 2015 financing round compared to the 2016 financing round.

Net cash provided by financing activities was $66.8 million in the twelve months ended December 31, 2015, an increase of $17.5 million from $49.3 million in the twelve months ended December 31, 2014. The increase was attributable primarily to our follow-on offering in April 2015 and the exercise of warrants and options.

Cash and funding sources

The table below summarizes our main sources of financing for the years ended December 31, 2016 and 2015:

	Proceeds from our public offerings[1]	Proceeds from issuance of ordinary shares[1]	Payments from licensees	Total
	(in thousands of US$)			
Year ended December 31, 2016	$54,132	$ 1,407	$ 2,575	$58,114
Year ended December 31, 2015	$64,202	$ 2,629	$ 1,063	$67,894
Year ended December 31, 2014	$41,092	$ 8,157 [2]	$ 4,052	$53,301

(1) Net of issuance costs.
(2) Issuance of preferred shares converted to ordinary shares.

Our sources of financing in the year ended December 31, 2016 totaled $58.1 million and consisted primarily of $54.1 million of net proceeds from our 2016 follow-on public offering.

Our sources of financing in the year ended December 31, 2015 totaled $67.9 million and consisted primarily of $64.2 million proceeds from our 2015 follow-on public offering.

We have no ongoing material financial commitments (such as lines of credit) that may affect our liquidity over the next five years.

Funding requirements

We believe, based on our current business plan, that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements throughout the Phase III clinical trials for our lead product candidate, FMX101, which we expect to complete by 2017. The full development and NDA submissions for FMX103 and any future pipeline products will require us to raise additional funds. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our present and future funding requirements will depend on many factors, including, among other things:

- the progress, timing and completion of preclinical testing and clinical trials for FMX101, FMX103 or any future pipeline product;
- selling, marketing and patent-related activities undertaken in connection with the anticipated commercialization of FMX101 and any other product candidates and costs involved in the development of an effective sales and marketing organization;
- the time and costs involved in obtaining regulatory approval for FMX101 and our other pipeline products and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these products;
- the number of potential new products we identify and decide to develop;

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- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights; and

- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of FMX101 and any other pipeline product that is commercialized.

For more information as to the risks associated with our future funding needs, see "Item 3.D. Risk Factors—We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts."

Our capital expenditures for 2016, 2015 and 2014 amounted to $424,000, $500,000, and $219,000, respectively. During 2016, these expenditures were primarily related to the purchase of laboratory equipment, computers, software and leasehold improvements.

5.C. Research and Development, Patents and Licenses, etc.

See "Item 4.B. Business Overview—Who we are—Development and license agreements" and "Item 4.B. Business Overview—Who we are—Intellectual Property."

5.D. Trend Information.

We are currently in the development stage and we expect to remain in that stage for the upcoming year, and therefore trends relating to production, sales, inventory, backlog and selling prices are not applicable.

5.E. Off-Balance Sheet Arrangements

We currently do not have any, and during the periods presented we did not have any, off-balance sheet arrangements.

5.F Contractual Obligations

Our significant non-cancelable contractual obligations as of December 31, 2016 are summarized in the following table.

	Payments due by period		
	Total	less than 1 year	1-3 years
	(in thousands of US$)		
Operating lease obligations[1]	$2,164	$ 498	$ 1,666
Bank borrowings[2]	$20	$ 20	-

(1) Operating lease obligations consist of lease of the Company's facilities.
(2) Current maturities of long term bank borrowings

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A. Directors and Senior Management

The following table sets forth information relating to our executive officers and directors as of December 31, 2016. Unless otherwise stated, the address for our directors and executive officers is c/o Foamix Pharmaceuticals Ltd., 2 Holzman St., Weizmann Science Park, Rehovot 7670402, Israel.

Name	Age	Position
Executive Officers		
Dov Tamarkin, Ph.D.	61	Chief Executive Officer and Director
Meir Eini	62	Chief Innovation Officer
David Domzalski	50	President, Foamix Pharmaceuticals Inc. (U.S. Subsidiary)
Ilan Hadar, M.B.A.	47	Chief Financial Officer
Yohan Hazot	34	Chief Technology Officer
David Schuz	62	Executive Vice President, Intellectual Property
Mitchell Shirvan, Ph.D., M.B.A.	63	Senior Vice President, Research and Development
Alvin Howard	62	Vice President, Regulatory Affairs (U.S. Subsidiary)
Herman Ellman, M.D.	69	Vice President, Clinical Affairs (U.S. Subsidiary)
Russell Elliott, D.Phil.	51	VP Drug Development (U.S. Subsidiary)
Iain A. Stuart, Ph.D.	44	Vice President, Clinical Development (U.S. Subsidiary)
Non-Employee Directors		
Stanley Hirsch, D.Phil.	58	Director, Chairman of the Board of Directors
Rex Bright	76	Director, Chairman of the Compensation Committee
Darrell Rigel, M.D.	66	Director
Stanley Stern	59	Director, Chairman of the Audit Committee

Anna Kazanchyan, Ph.D.	49	Director
Aaron Schwartz, Ph.D.	75	Director
Dalia Megiddo, Ph.D., M.B.A.	64	Director

Our executive officers

Dov Tamarkin, Ph.D. has been serving as our Chief Executive Officer and as our director since January 2003. Prior to that, Dr. Tamarkin served as Vice President of R&D at Portman Pharmaceuticals, Inc., a biotech research and development company and as Senior R&D Manager at Teva Pharmaceutical Industries Ltd., a public Israeli pharmaceutical company. Dr. Tamarkin holds a Ph.D. in chemistry from The Hebrew University of Jerusalem.

Meir Eini served as chairman of our board of directors from January 2003 through May 2016. Mr. Eini simultaneously served as our Chief Operations Officer from January 2003, and since 2014 he has been serving as the Company's Chief Innovation Officer. Since stepping down from his positon as chairman of the board, Mr. Eini continues to serves as a non-voting observer to the board, a capacity in which he is entitled to attend meetings and receive all notices and other correspondence and communications sent by us to the directors. Mr. Eini has 27 years of experience in healthcare and marketing and is an experienced entrepreneur. Between 2000 and 2003, Mr. Eini founded and served as the Chief Executive Officer of Flexiprobe Ltd., the developer of a medical device for women's health. Prior to that, Mr. Eini was the Founder and President of Clilco Ltd., a company engaged in the development and commercialization of non-prescription pharmaceuticals, and was the Founder of Thixo Ltd., an oilgel food technology company.

David Domzalski has been serving as the President of our U.S. subsidiary, Foamix Pharmaceuticals, Inc., since April 2014. Mr. Domzalski has 24 years of industrial experience, previously holding positions as Vice President Sales and Marketing at LEO Pharma Inc. from 2009 to 2013, Senior Vice President and General Manager at Azur Pharma from 2008 to 2009, and Vice President Sales and Marketing at Warner Chilcott from 2003 to 2008. Mr. Domzalski holds a B.A. in economics and political science from Muhlenberg College, Allentown, Pennsylvania.

Ilan Hadar has been serving as our Chief Financial Officer since February 2014. Mr. Hadar has extensive experience in executive financial positions, previously holding positions as Finance Director of the Israeli subsidiary of Pfizer from 2011 to 2013, as Finance Manager, Accounting and Reporting at the Israeli subsidiary of HP from 2007 to 2011, and prior to that as Finance Director of the Israeli subsidiary of BAE Systems. Mr. Hadar holds a B.A. in business administration and economics and an MBA from The Hebrew University of Jerusalem.

Yohan Hazot has been serving as our Chief Technology Officer since December 2014. Mr. Hazot has been with the Company since April 2007, and has held several positions in the field of drug development and intellectual property, with his previous position being a Director of Pharmaceutical Development. Mr. Hazot holds an MSc in Biochemistry & Biotechnology from the National Institute of Applied Sciences, Lyon, France and is the inventor of several patents in the field of Pharmaceutical Chemistry.

David Schuz has been serving as our Executive Vice President since 2010 and as our Senior Vice President for intellectual property since 2006. Mr. Schuz has 22 years of experience in the field of intellectual property in relation to the pharmaceuticals and biotechnology industries, previously holding various intellectual property and legal positions at Biotechnology General Israel Ltd. and Savient Pharmaceuticals, Inc. between 1996 and 2006, including Vice President from 2003. Mr. Schuz holds an LL.M. from the London School Economics; a Certificate in Patent Law, Queen Mary London University; an M. Phil. (Biochemistry), and a Diploma of Pharmacology, both from Cambridge University; and a B.Sc. Hons. (Chemistry) from Manchester University.

Mitchell Shirvan, Ph.D. has been serving as our Senior Vice President of Research and Development since March 2014. Dr. Shirvan has over 21 years of experience in the pharmaceuticals and biotechnology industry, previously holding positions of Chief Executive Officer at Macrocure Ltd. from 2008 to 2012 and as Senior Director, Strategic Business Planning and Senior Manager, Research and Development at Teva Pharmaceutical Industries between 1992 and 2008. Dr. Shirvan holds a Ph.D. in microbiology from The Hebrew University of Jerusalem, and an MBA from the University of Bradford.

Alvin Howard has been serving as Vice President of Regulatory Affairs of our U.S. subsidiary, Foamix Pharmaceuticals, Inc., since April 2014. Mr. Howard has over 31 years of industry experience, previously holding positions as Senior Vice President of Regulatory Affairs in Warner Chilcott from 2005 to 2013, Vice President of Regulatory Affairs at Roberts Pharmaceuticals from 1998 to 2000 and various positions at Solvay Pharmaceuticals from 1990 to 1998. Mr. Howard holds a B.Sc. in chemistry from Stillman College, Tuscaloosa, Alabama.

Herman Ellman, M.D. has been serving as Vice President of Clinical Affairs of our U.S. subsidiary, Foamix Pharmaceuticals, Inc., since April 2014. Dr. Ellman has over 26 years of experience in the pharmaceutical industry, previously holding positions as Senior Vice President for Clinical Development at Warner Chilcott from 2000 to 2013 and Medical Director at Berlex Laboratories from 1995 to 2000. Dr. Ellman holds a M.D. from the State University of New York, Downstate Medical Center and Boards in Internal Medicine, Pulmonary Diseases and Critical Care Medicine.

Russell Elliott, D.Phil. has served as Vice President of Drug Development of our U.S. subsidiary, Foamix Pharmaceuticals, Inc. since May 2016. Dr. Elliott has over 25 years of experience in the pharmaceutical industry, previously holding the position of Vice President Product Development at Stiefel. Prior to this, Dr. Elliott served as Vice President and Head of Center of Excellence for topical formulations at GSK. Dr. Elliott holds a D. Phil from the Oxford University in the U.K.,

Iain Stuart, Ph.D. has served as Vice President of Clinical Development of our U.S. subsidiary, Foamix Pharmaceuticals, Inc. since October 2016. Dr. Stuart has over 18 years of clinical development scientific affairs experience in multiple therapeutic classes with the last 8 years being focused exclusively in dermatology. Prior to joining Foamix, Dr. Stuart served as Vice President of Medical Strategy and Scientific Affairs at LEO Pharma. Prior to this, Dr. Stuart served as Director, Clinical Operations – The Americas, also at LEO Pharma. Dr. Stuart holds a Ph.D. from Glasgow Caledonian University in Scotland.

Our directors

Stanley Hirsch, D.Phil. has been serving as our director since February 2005 and as chairman of the board since May 2016. Dr. Hirsch has 30 years of experience in executive positions, including director of business development for a privately held group of healthcare companies. He has also served as general manager of two diagnostics development companies. Dr. Hirsch has been CEO at FuturaGene Ltd., and its predecessor company CBD Technologies Ltd., since 1989, and has also held the position of General Manager of Portman Pharmaceutical Industries. Since the acquisition of FuturaGene Plc by Suzano Pulp and Paper, a major Brazilian industrial public corporation in July 2010, he also holds the equivalent position of a vice president at Suzano, reporting to the CEO at Suzano. Dr. Hirsch holds a D. Phil in Cell Biology and Immunology from Oxford University, England.

Rex Bright has been serving as our director since our initial public offering that was completed in September 2014. Mr. Bright has held CEO positions in the health care industry for the past 21 years. Mr. Bright was the co-founder and CEO of SkinMedica, a specialty pharmaceutical business that was later acquired by Allergan. Mr. Bright has worked in executive positions for Johnson & Johnson and GlaxoSmithKline. Mr. Bright holds a B.A. in Business Administration and Marketing from Drury College, Springfield, Missouri.

Aaron Schwartz, Ph.D. has been serving as our director since May, 2015. Dr. Schwartz served in a number of positions at Teva Pharmaceutical Industries Ltd. from 1975 through 2011. After serving 7 years as the head of the pharmaceutical division of Teva in Israel, Dr. Schwartz created the Copaxone division of Teva in 1992 and led it for 9 years. His most recent position was Vice President, Head of Teva Innovative Ventures - TIV, which he held from 2008 to 2011. Dr. Schwartz is currently chairman of the board for several life science companies. Dr. Schwartz received a Ph.D. in organic chemistry from the Weizmann Institute, an M.Sc. in organic chemistry from the Technion and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem. He recently received a second Ph.D. from the Hebrew University of Jerusalem in history and philosophy of science.

Anna Kazanchyan, M.D. has been serving as our director since December 2014. Dr. Kazanchyan is a biotechnology executive with more than 16 years of experience at Wall Street firms, biopharmaceutical companies and as an entrepreneur. Dr. Kazanchyan is the founder and Managing Partner of Primary i-Research, LLC, where she provides due diligence to leading healthcare investment funds and evaluates investment prospects of biopharmaceutical companies based on the scientific, clinical, regulatory, and commercial outlook for their products. In addition, she has been a strategic advisor to CEOs of biopharmaceutical companies (start-ups to global companies) and has advised companies on matters related to business development, regulatory strategy, marketing and commercial/competitive landscape. Previously, Dr. Kazanchyan was Senior Biotechnology Analyst at Wachovia Securities, and was a member of the biotechnology equity research teams at Goldman Sachs and Citigroup. She received an M.D. from Harvard Medical School and a B.A. in biology, summa cum laude, from Clark University.

Darrell Rigel, M.D. has been serving as our director since our initial public offering that was completed in September 2014. Dr. Rigel is a Clinical Professor of Dermatology at the New York University Medical School, an Adjunct Clinical Professor of Dermatology at the Mount Sinai School of Medicine, as well as being an Attending at the Tisch and Bellevue Hospitals in New York. Dr. Rigel holds an SB in Management Information Sciences and an SM in Management Information Science from the Massachusetts Institute of Technology and an M.D. from the George Washington University School of Medicine.

Stanley Stern has been serving as our director since our initial public offering that was completed in September 2014. Mr. Stern has 32 years of experience as an investment banker, working primarily for Oppenheimer & Co, in a number of positions including head of investment banking. He also worked for STI Ventures, Salomon Brothers and C.E. Unterberg. In 2013, Mr. Stern founded Alnitak Capital Partners which provides strategic advice and conducts merchant banking activities. Mr. Stern holds a B.A. in Economics and Accounting from City University of New York, Queens College, and an M.B.A. from Harvard University. He currently serves as chairman of Audiocodes (AUDC) and Sodastream (SODA) and also serves as a director of Ormat Technologies and Ekso Bionics. He previously served as a director of Given Imaging and Fundtech.

Dalia Megiddo, M.D. has been serving as our director since May 2016. Dr. Megiddo co-founded a number of pharma companies, including Alcobra Ltd. (Nasdaq: ADHD), Bioblast-Pharma Ltd. (Nasdaq: ORPN) and Chiasma Ltd. (Nasdaq: CHMA). She currently serves as Managing Partner of Expedio Ventures, and previously ran other life science investment funds, including Jerusalem Global Ventures and 7-Health. Dr. Megiddo serves as a director of Bioblast-Pharma Ltd. She formerly served as a director of Alcobra Ltd., AngioScore Inc., Chiasma (Israel) Ltd., Chiasma Inc., Given Imaging Ltd. (Nasdaq: GIVN) and Elron Electronic Industries Ltd. (Nasdaq: ELRN). Dr. Megiddo holds an M.D. in Medicine from Hebrew University, Jerusalem, and is a licensed specialist in family medicine. She also holds an M.B.A. degree from the Kellogg Recanati International School of Business (Tel Aviv University and North Western University).

Observers to the board of directors

Chaim Chizic, who served as a director of the Company until June 2015, currently serves as a non-voting observer to our board of director. In such capacity Mr. Chizic may attend meetings of the board and is entitled to receive all notices and other correspondence and communications sent by us to members of our board of directors. In addition, he receives compensation equal to the compensation we pay our directors.

Meir Eini -- see above disclosure regarding Mr. Eini's role as an observer to the board in "Item 6.A. Directors and Senior Management—Our executive officers—Meir Eini".

Arrangements concerning election of directors; family relationships

We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

6.B. Compensation

Compensation of executive officers and directors

The following table summarized the compensation awarded to, earned by, or paid to each of our five most highly compensated directors and executive officers during the twelve months ended on December 31, 2016 (in thousands of U.S. dollars):

Name	Position	Salary[1]	Bonus	Value of Equity Awards Granted[2]	Other Compensation[3]	Total
		(in thousands of US$)				
Dr. Dov Tamarkin	CEO	$385	$352	$ 239	$ 207	$1,183
David Domzalski	President of Foamix U.S.	370	225	446	-	1,041
Meir Eini	Chief Innovation Officer	300	165	203	158	826
Ilan Hadar	CFO	240	173	318	81	812
Alvin Howard	VP Regulatory Affairs U.S.	$307	$98	$ 179	$ -	$584

(1) Salary paid in Israeli Shekels is shown in the table in U.S. dollars based on the average exchange rate of 2016.

(2) The value of options and RSUs shown in this column is the expense recorded in our financial statements for the period ended December 31, 2016, with respect to all options and RSUs granted to such executive officer.

(3) The amounts reported in the All Other Compensation consist of social benefits, medical coverage expenses and car allowance.

The aggregate compensation paid and equity-based compensation and other payments expensed by us to all of our directors and executive officers with respect to the year ended December 31, 2016 was $7.2 million. This amount does not include business travel, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

As of December 31, 2016, options and Restricted Stock Units, or RSUs, for a total of 2,013,913 ordinary shares granted to our directors and executive officers were outstanding under our 2009 and 2015 Plans. The weighted average exercise price of options as of December 31, 2016, was $5.74 per share.

6.C. Board practices

Board of directors

Under the Israeli Companies Law, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to the employment agreement that we have entered into with him. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association, our board of directors must consist of at least five and not more than nine directors. The Israeli Companies Law and our amended and restated articles of association provide that directors are elected annually at the general meeting of our shareholders by a vote of the holders of a majority of the voting power represented present and voting, in person or by proxy, at that meeting. We have only one class of directors.

In August 2016, our board of directors resolved, in accordance with the Israeli Companies Regulations (Concessions for Companies Whose Shares are Listed for Trading on a Stock Exchange Abroad), 5760-2000, or the Concession Regulations, as amended on April 17, 2016, to "opt out" from certain requirements of the Israeli Companies Law, 5759-1999, or the Companies Law, with regard to (i) the appointment of external directors; (ii) certain restrictions on the engagement of external directors and their relatives and affiliates following the end of their tenure, and (iii) the composition and quorum of the audit committee and compensation committee. Under the Concession Regulations, these concessions will continue to be available to the Company so long as: (i) its shares are traded on a U.S. stock exchange, including the NASDAQ Global Market; (ii) it does not have a "controlling shareholder" (as such term is defined under the Companies Law), and (iii) it complies with the majority board independence requirements and audit committee and compensation committee requirements under U.S. laws applicable to U.S. domestic issuers. External directors who were appointed prior to the date on which our board decided to opt out of the requirement to maintain such function may continue to hold their office until the earlier of the expiry of their original 3-year term or the second annual shareholder meeting held after such decision was taken.

Our board of directors has determined that seven of our directors (namely – all directors apart from Dr. Dov Tamarkin) are independent under the NASDAQ Stock Market rules.

In accordance with the exemption available to foreign private issuers, we do not follow the requirements of the NASDAQ rules with regard to the process of nominating directors, and instead, follow Israeli law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election.

Under the Israeli Companies Law and our amended and restated articles of association, nominees for directors may also be proposed by any shareholder holding at least one percent (1%) of our outstanding voting power. However, any such shareholder may propose a nominee only if a written notice of such shareholder's intent to propose a nominee has been given to our Secretary (or, if we have no such Secretary, our Chief Executive Officer). Any such notice must include certain information, including, among other things, a description of all arrangements between the nominating shareholder and the proposed director nominee and any other person pursuant to which the nomination is to be made by the nominating shareholder, the consent of the proposed director nominee to serve as our director if elected and a declaration signed by the nominee declaring that there is no limitation under the Israeli Companies Law preventing his or her election, and that all of the information that is required under the Israeli Companies Law to be provided to us in connection with such election has been provided.

In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, for a term of office equal to the remaining period of the term of office of each director whose office has been vacated. Vacancies on our board of directors may be filled by a vote of a simple majority of the directors then in office. A director so appointed will hold office until the next annual general meeting of our shareholders in which the other directors then in office are proposed to be replaced or reappointed.

Under the Israeli Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is one.

Chairman of the board

In accordance with the Israeli Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Dr. Stanley Hirsch to serve as chairman of the board of directors.

Board Committees

Audit committee

Israeli Companies Law requirements

Under the Israeli Companies Law, we are required to have an audit committee. However, following the decision of our board of directors to opt out of the various restrictions concerning the composition of the audit committee under the Israeli Companies Law, the composition of our audit committee and the nomination of members to such committee are now governed by the regulations of the U.S. Securities Exchange Commission, or SEC, and the NASDAQ Stock Market rules, as set out below.

NASDAQ listing requirements and SEC regulations

Under the NASDAQ Stock Market rules and SEC regulations, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

In order for a director to be designated as "independent" under the NASDAQ Stock Market rules and SEC regulations, he or she must not have a material relationship with the company that would impair his or her independence, such as a commercial, consulting, legal, accounting or familial relationships, among others. However, ownership of a significant amount of shares or affiliation with a major shareholder should not, in and of itself, preclude the board from determining that a director is independent, nor is the board precluded from appointing its chairman as a member of the audit committee or as chairman of the committee.

In order for a director to be designated as "financially literate" under the NASDAQ Stock Market rules and SEC regulations, he or she are required to have sufficient understanding of the language of accounting and corporate finance to act as effective overseers of the integrity of a company's financial reporting process and its financial statements, including the selection and oversight of the performance of the external and internal auditors.

In order for a director to qualify as an "audit committee financial expert" under SEC regulations he or she must have education and experience as chief financial officer, chief accounting officer, controller, public accountant or auditor, or experience in one or more positions that involve the performance of similar functions or in actively supervising such positions. If no audit committee member qualifies, the company must state why its audit committee lacks a financial expert.

Our audit committee consists of Stanley Stern (Chairman), Rex Bright and Darrell Rigel. Each of the members of our audit committee is eligible to be classed as an independent director in accordance with SEC regulations and satisfies the independent director requirements under the NASDAQ Stock Market rules. All designated members of our audit committee meet the requirements for financial literacy under the applicable rules of the NASDAQ Stock Market and SEC regulations. However, we do not currently have an audit committee financial expert as such term is defined by the SEC. Nevertheless, our board of directors has determined in its business judgment that our existing committee members have the ability to oversee our financial statements based on their extensive business backgrounds and that Stanley Stern has "financial sophistication" under the NASDAQ Stock Market rules.

Audit committee roles

Our board of directors has adopted an audit committee charter that sets forth the responsibilities of the audit committee consistent with the rules and regulations of the SEC and the NASDAQ Stock Market rules, as well as the requirements for such committee under the Israeli Companies Law, including the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Israeli Companies Law, our audit committee is responsible for:

i. determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;

ii. determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under the Israeli Companies Law) (see our Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Management—Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers");

iii. establishing the approval process (including, potentially, the approval of the audit committee) for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest;

iv. where the board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board of directors and proposing amendments thereto

v. examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his responsibilities;

vi. examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and

vii. establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Our audit committee may not approve any actions requiring its approval (see our Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Management—Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers"), unless at the time of the approval a majority of the committee's members are present, which majority consists of independent directors.

Agreements with executive officers; consulting and directorship services provided by directors

We have entered into written employment agreements with all of our executive officers. These agreements contain standard provisions for a company in our industry regarding non-solicitation, confidentiality of information, non-competition and assignment of inventions. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment, which varies for each individual.

Compensation committee and compensation policy

Following the Concession Regulations and the decision of our board of directors to opt out of the requirements concerning the appointment of a compensation committee under the Israeli Companies Law, the company is only required to comply with the requirements regarding such appointment under the NASDAQ Stock Market rules. Accordingly, we have established and continue to maintain a compensation committee, the members of which are currently Rex Bright (Chairman), Darrel Rigel, Stanley Stern and Anna Kazanchyan. Each member of our compensation committee is independent under the NASDAQ Stock Market rules.

The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought for approval by the company's shareholders, referred to herein as the Special Majority Approval for Compensation. A Special Majority Approval for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (i) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement; or (ii) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average compensation of the other employees of the company, including those employed through manpower companies
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;

- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;

- the minimum holding or vesting period for variable, equity-based compensation; and

- maximum limits for severance compensation

The compensation committee is responsible for (i) recommending the compensation policy to a company's board of directors for its approval (and subsequent approval by its shareholders) and (ii) duties related to the compensation policy and to the compensation of a company's office holders as well as functions previously fulfilled by a company's audit committee with respect to matters related to approval of the terms of engagement of office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);

- recommending to the board of directors periodic updates to the compensation policy;

- assessing implementation of the compensation policy; and

- determining whether the compensation terms of the chief executive officer of the company need not be brought to approval of the shareholders

Our compensation committee, board of directors and shareholders approved our compensation policy.

Compensation committee roles

Our board of directors has adopted a compensation committee charter setting forth the responsibilities of the compensation committee, which include:

- the responsibilities set forth in the compensation policy;

- reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by our board of directors; and

- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

Internal auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. An internal auditor may not be:

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

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

- an office holder (including a director) of the company (or a relative thereof); or

- a member of the company's independent accounting firm, or anyone on its behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. We have appointed an internal auditor.

Exculpation, Insurance and Indemnification of Directors and Officers

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

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

- financial liability 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 (1) 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; and (2) in connection with a monetary sanction; and

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

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

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli 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 to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm 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 illegal personal benefit; or
- a fine or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders.

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

We have obtained directors and officers liability insurance for the benefit of our office holders and have increased such coverage to $25 million per annum. We intend to maintain such increased coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, we have entered into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association and Israeli Law.

6.D. Employees

As of December 31, 2016, we had 68 employees, 57 are based in Israel and 11 are based in the U.S. The distribution of our full-time employees according to main areas of activity is set forth in the following table:

	Employees
Area of Activity:	
Research and development	50
Selling, general and administrative	18
Total	68

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is party to any collective bargaining agreements, certain provisions of the 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 in Israel by order of the Israeli Ministry of the Economy. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. 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 relationships with our employees are good.

6.E. Share ownership

The following table provides information with respect to our securities beneficially owned by our directors and executive officers who hold more than 1% of our outstanding shares, as of December 31, 2016:

* Less than one percent

Name	Type of Security	Number of Securities	Options/Warrants Exercise Price ($)	Options/Warrants Exercise Date	Percent of Shares Outstanding	
Dr. Dov Tamarkin[1]	Shares	2,750,689	-	-	7.6	%
	Warrants	2,094	$5.04	April 9, 2018		
	Options	24,000	5.88	December 29, 2024		
	Options	45,000	6.77	December 28, 2024		
	Options	100,000	6.34	March 1, 2026		
	RSUs	9,000	-	-		
Meir Eini[2]	Shares	2,896,781	-	-	8.0	%
	Warrants	20,860	$5.04	April 9, 2018		
	Options	48,000	5.88	December 29, 2024		
	Options	36,000	6.77	December 28, 2024		
	Options	35,000	7.09	August 9, 2026		
	RSUs	9,000	-	-		
	RSUs	20,000	-	-		
David Domzalski				-	*	
Ilan Hadar				-	*	
Alvin Howard				-	*	

* Less than one percent

(1) Dr. Dov Tamarkin ("Tamarkin"), our co-founder, Chief Executive Officer and director owns our securities indirectly through Tamarkin Medical Innovation, Ltd. an Israeli company owned and controlled by Tamarkin.

(2) Meir Eini ("Eini"), our co-founder and Chief Innovative Officer owns our securities indirectly through Meir Eini Holdings Ltd., an Israeli company owned and controlled by Eini.

Other directors and officers beneficially own securities that represent less than 1% of our share capital.

2009 Israeli Share Option Plan

In July 2009, we adopted our 2009 Israeli Share Option Plan, or the 2009 Plan. The 2009 Plan provides for the grant of options to our and our subsidiaries' directors, employees, officers, consultants and service providers, among others.

The 2009 Plan is administered by our board of directors or a committee designated by our board of directors, which determines, subject to Israeli law, the grantees of options, the terms of the options, including exercise or purchase prices, vesting schedules, acceleration of vesting, the type of option and the other matters necessary or desirable for, or incidental to the administration of the 2009 Plan. The 2009 Plan provides for the issuance of options under various tax regimes including, without limitation, pursuant to Sections 102 and 3(i) of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance. Any options that expire or are canceled for any reason prior to their exercise or relinquishment in full may once again be granted pursuant to options under the 2009 Plan. If our outstanding shares are changed or exchanged at any time by declaration of a share dividend, share split, combination or exchange of

shares, recapitalization or any similar event, then the number, class and kind of shares subject to the 2009 Plan, the options granted under the 2009 Plan and the applicable exercise prices will be proportionally adjusted.

Section 102 of the Ordinance allows employees, directors and officers, who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares or options. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee.

Section 102(b)(2) of the Ordinance, which provides the most favorable tax treatment for grantees, permits the issuance to a trustee under the "capital gains track." In order to comply with the terms of the capital gains track, all options granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such options and other shares received following any realization of rights with respect to such options, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant employee, director or officer. The trustee may not release these options or shares to the relevant grantee before the second anniversary of the issuance and deposit of the options with the trustee. However, under this track, we are not allowed to deduct an expense with respect to the issuance of the options or shares.

The 2009 Plan provides that options granted to our employees, directors and officers who are not controlling shareholders and who are considered Israeli residents may qualify for special tax treatment under the "capital gains track" provisions of Section 102(b)(2) of the Ordinance. Our Israeli non-employee service providers and controlling shareholders may only be granted options under Section 3(i) of the Ordinance, which does not provide for similar tax benefits.

Options granted under the 2009 Plan are subject to vesting schedules and vest over a four-year period commencing on the date of grant, such that 20% of the granted options are fully vested as of the date of the grant and thereafter 5% of the granted options vest upon the lapse of each three-month period. Options generally expire 10 years from approval of their approval. Under the 2009 Plan, in the event of termination of employment or services for reasons of disability or death, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within a period of 12 months after the date of termination. If a grantee's employment or service is terminated for cause, as defined in the 2009 Plan, all of the grantee's vested and unvested options expire or forfeited on the date of termination. If a grantee's employment or service is terminated without cause, the grantee may exercise his or her vested options within 90 days after the date of termination. Any expired, forfeited or unvested options are returned to the pool for reissuance.

The 2009 Plan provides that in the event of a merger or consolidation of our company, or a sale of all, or substantially all, of our assets, the unexercised options outstanding may be assumed, or substituted for an appropriate number of shares of each class of shares or other securities as were distributed to our shareholders in connection with such transaction and the exercise price will be appropriately adjusted. If not so assumed or substituted, all non-vested and non-exercised options will expire upon the closing of the transaction. Our board of directors or its designated committee, as applicable, may provide in the option agreement that if the acquirer does not agree to assume or substitute the options, vesting of the options shall be accelerated so that any unvested option or any portion thereof will vest generally 10 days prior to the closing of the transaction. In the event that such consideration received in the transaction is not solely in the form of ordinary shares of another company, the board of directors or the designated committee, as applicable, may, with the approval of the acquirer, provide that in lieu of the assumption or substitution of the options, the options will be substituted by another type of asset or property, including cash. If we are voluntarily liquidated or dissolved, option holders will have 10 days to exercise any then-vested options upon receiving notification from us of the liquidation or dissolution.

The board may amend, alter, suspend or terminate the 2009 Plan at any time. However no amendment, alteration, suspension or termination may impair the rights of any option holder under the 2009 Plan unless agreed upon in writing by us and the affected option holder.

Since the adoption of the 2015 Plan (see below), the Company stopped granting options under the 2009 Plan.

2015 Israeli Share Incentive Plan

In May 2015, we adopted our 2015 Israeli Share Incentive Plan, or the 2015 Plan. The 2015 Plan provides for the grant of options to our and our subsidiaries' directors, employees, officers, consultants and service providers, among others. As of the adoption of the 2015 Plan, all new grants of options and RSUs are made pursuant to the 2015 Plan.

The 2015 Plan is administered by our board of directors or a committee designated by our board of directors, which determines, subject to Israeli or US law (as applicable), the grantees of options or RSUs (collectively – Awards), the terms of the Awards including exercise prices (with regard to options), vesting schedules, acceleration of vesting, the type of Award and the other matters necessary or desirable for, or incidental to the administration of the 2015 Plan. The 2015 Plan also authorizes our board of directors or a committee designated by our board of directors to allow net exercise of options. The 2015 Plan provides for the issuance of Awards under various tax regimes including, without limitation, pursuant to Sections 102 and 3(i) of the Ordinance. Any Awards that expire or are canceled for any reason prior to their exercise or relinquishment in full may once again be granted under the 2015 Plan. If our outstanding shares are changed or exchanged at any time by declaration of a share dividend, share split, combination or exchange of shares, recapitalization or any similar event, then the number, class and kind of shares subject to the 2015 Plan, the Awards granted under the 2015 Plan and the applicable exercise prices will be proportionally adjusted.

The 2015 Plan provides that Awards granted to our employees, directors and officers who are not controlling shareholders and who are considered Israeli residents may qualify for special tax treatment under the "capital gains track" provisions of Section 102(b)(2) of the Ordinance. Our Israeli non-employee service providers and controlling shareholders (if any) may only be granted options under Section 3(i) of the Ordinance, which does not provide for similar tax benefits.

Awards granted under the 2015 Plan are subject to vesting schedules and generally expire 10 years from approval of the Award. The vesting periods or vesting conditions (e.g. performance-based vesting) may be set by our board of directors or a committee designated by our board of directors. Under the 2015 Plan, in the event of termination of employment or services for reasons of disability or death, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within a period of 12 months after the date of termination. If a grantee's employment or service is terminated for cause, as defined in the 2015 Plan, all of the grantee's vested and unvested Awards expire on the date of termination. If a grantee's employment or service is

terminated without cause, the grantee may exercise his or her vested Awards within 90 days after the date of termination. Any expired or unvested Awards are returned to the pool for reissuance.

The 2015 Plan provides that in the event of a merger or consolidation of our company, or a sale of all, or substantially all, of our assets, the unexercised Awards outstanding may be assumed, or substituted for an appropriate number of shares of each class of shares or other securities as were distributed to our shareholders in connection with such transaction and the exercise price will be appropriately adjusted. If not so assumed or substituted, all non-vested and non-exercised Awards will expire upon the closing of the transaction. Our board of directors or its designated committee, as applicable, may provide in the Award agreement that if the acquirer does not agree to assume or substitute the options, vesting of any or all of such Awards shall be accelerated so that any unvested Award or any portion thereof will vest generally 10 days prior to the closing of the transaction. In the event that such consideration received in the transaction is not solely in the form of ordinary shares of another company, the board of directors or the designated committee, as applicable, may, with the approval of the acquirer, provide that in lieu of the assumption or substitution of the Awards, the Awards will be substituted by another type of asset or property, including cash. If we are voluntarily liquidated or dissolved, Award holders will have 10 days to exercise any then-vested Awards upon receiving notification from us of the liquidation or dissolution.

The board may amend, alter, suspend or terminate the 2015 Plan at any time. However no amendment, alteration, suspension or termination may impair the rights of any option holder under the 2015 Plan unless agreed upon in writing by us and the affected option holder.

As of December 31, 2016, there were 184,733 RSUs and 2,514,142 options outstanding under the 2009 and 2015 Plans. The weighted average exercise price of these options was $5.7. Out of awards granted, 90,117 RSUs and 69,444 options were exercised. As of December 31, 2016, 845,858 Awards remain available for grant under the 2015 Plan.

In November, 2016 the board of directors approved an increase of 900,000 ordinary shares, to a total of 1,745,858 awards remain available for grant under the 2015 Plan. The shares were registered in January 2017.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

The following table sets forth information regarding the beneficial ownership by each person or entity known to beneficially own more than 5% of our ordinary shares and of our directors and officers as of December 31, 2016, or a different date, if so provided in the table below or footnotes thereof.

According to our transfer agent, as of December 31, 2016, there were 9 record holders of our ordinary shares, among whom two (including Cede & Co.) are U.S. holders who beneficially own in the aggregate 37,167,791 of our ordinary shares. None of our shareholders has different voting rights from other shareholders.

We are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is: c/o 2 Holzman St., Weizmann Science Park, Rehovot 7670402, Israel

Name	Number and Percentage of Ordinary Shares	
	Number	Percent
5% or Greater Shareholders (other than directors and executive officers)		
Baker Bros. Advisors (GP) LLC [(1)]	2,046,967	6.6 %
Great Point Partners, LLC [(2)]	2,769,425	7.5 %
Directors and Executive Officers		
Dr. Dov Tamarkin[(3)]	2,750,689	7.6 %
Meir Eini[(4)]	2,896,781	8.0 %
Dr. Stanley Hirsch[(5)]	*	-
David Schuz[(6)]	*	-
Dr. Mitchell Shirvan[(7)]	*	-
Ilan Hadar[(8)]	*	-
David Domzalski[(9)]	*	-
Alvin Howard[(10)]	*	-
Dr. Herman Ellman[(11)]	*	-
Rex Bright[(12)]	*	-
Dr. Darrell Rigel[(13)]	*	-

Stanley Stern[14]	*	-	
Dr. Anna Kazanchyan[15]	*	-	
Yohan Hazot[16]	*	-	
Dr. Aaron Schwartz[17]	*	-	
All Directors and Executive Officers as a Group[18]	6,567,063	17.3	%

*Less than 1%

(1) Based on information contained in Schedule 13G filed with the SEC on February 16, 2016 jointly by Baker Bros. Advisors LP, a limited partnership organized under the laws of the State of Delaware (the "Adviser"), Baker Bros Advisors (GP) LLC, a limited liability company organized under the laws of the State of Delaware (the "Adviser GP"), Felix J. Baker, a U.S. citizen and Julian C. Baker, a U.S. citizen (in this footnote, collectively with the Adviser and the Adviser GP, the "Reporting Persons"). Pursuant to that Schedule 13G, 165,124 ordinary shares are held directly by 667 L.P. and 1,881,843 ordinary shares are held by Baker Brothers Life Sciences, L.P. (collectively, the "Funds"). Pursuant to an amended and restated management agreements among the Adviser, the Funds and their respective general partners, the Funds' respective general partners relinquished to the Adviser all discretion and authority with respect to the investment and voting power of the securities held by the Funds, and the Adviser has complete and unlimited discretion and authority with respect to the Funds' investments and voting power over investments. The business address of each of the Reporting Persons is c/o Baker Bros. Advisors LP, 667 Madison Avenue, 21st Floor, New York, NY 10065.

(2) Based on information contained in Schedule 13G filed with the SEC on October 11, 2016 jointly by Great Point Partners LLC, a limited liability company organized under the laws of the State of Delaware ("Great Point"), Dr. Jeffery R. Jay, M.D., a U.S. citizen ("Dr. Jay"), and Mr. David Kroin, a U.S. citizen ("Mr. Kroin", and collectively with Dr. Jay and Great Point, in this footnote, the "Reporting Persons"). Pursuant to that Schedule 13G (i) Biomedical Value Fund, L.P. ("BVF") is the record owner of 727,127 ordinary shares (the "BVF Shares"). Great Point is the investment manager of BVF. Each of Dr. Jay, as senior managing member of Great Point, and Mr. Kroin, as special managing member of Great Point, has voting and investment power with respect to the BVF Shares, (ii) Biomedical Offshore Value Fund, Ltd. ("BOVF") is the record owner of 1,047,995 ordinary shares (the "BOVF Shares"). Great Point is the investment manager of BOVF, and each of Dr. Jay, as senior managing member of Great Point, and Mr. Kroin, as special managing member of Great Point, has voting and investment power with respect to the BOVF Shares, (iii) GEF-SMA, LP ("GEF-SMA") is the record owner of 812,519 shares of ordinary shares (the "GEF-SMA Shares"). Great Point is the investment manager of GEF-SMA and each of Dr. Jay, as senior managing member of Great Point, and Mr. Kroin, as special managing member of Great Point, has voting and investment power with respect to the GEF-SMA Shares, and (iv) Class D Series of GEF-PS, L.P. ("GEF-PS") is the record owner of 181,784 shares of ordinary shares (the "GEF-PS Shares"). Great Point is the investment manager of GEF-PS and each of Dr. Jay, as senior managing member of Great Point, and Mr. Kroin, as special managing member of Great Point, has voting and investment power with respect to the GEF-PS Shares. The business address of each of the Reporting Persons is 165 Mason Street, 3rd Floor, Greenwich, CT 06830.

(3) Tamarkin Medical Innovation Ltd., is an Israeli company controlled by Dr. Dov Tamarkin, our co-founder, Chief Executive Officer and director. Consists of (i) 2,749,564 ordinary shares; (ii) 2,094 ordinary shares issuable upon exercise of outstanding warrants at a price of $5.04 per share (iii) 24,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share; (iv) 45,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share and (v) 100,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.34 per share and (vi) 1,125 ordinary shares issued upon vesting of outstanding RSUs. The address of Tamarkin Medical Innovation Ltd. is 537 Har Hila St., Modiin-Maccabim-Reut 7179901, Israel.

(4) Meir Eini Holdings Ltd., is an Israeli company controlled by Meir Eini, our co-founder and Chief Innovation Officer. Consists of (i) 2,895,656 ordinary shares (ii) 20,860 ordinary shares issuable upon exercise of outstanding warrants at a price of $5.04 per share (iii) 48,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share and (iv) 36,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share, and (v) 35,000 ordinary shares issuable upon exercise of outstanding options at a price of $7.09 per share, and (vi) 1,125 ordinary shares issued upon vesting of outstanding RSUs. The address of Meir Eini Holdings Ltd. is 2 Hashaked St., Ness-Ziona 7408711, Israel.

(5) Consists of (i) 6,448 ordinary shares (ii) 6,224 ordinary shares issuable upon exercise of outstanding warrants at a price of $5.04 per share; and (iii) 197,500 ordinary shares issuable to ZEAS Technology and Science Management Ltd., a company beneficially owned by Stanley Hirsch, upon exercise of outstanding options at a price of $0.62 per share, and (iv) 27,000 ordinary shares issuable upon vesting of outstanding options at a price of $5.88 per share.

(6) Consists of (i) 3,936 ordinary shares (ii) 64,188 ordinary shares issuable upon exercise of outstanding options at a price of $1.92 per share (iii) 9,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share, and (iv) 3,499 ordinary shares issuable upon exercise of outstanding options at a price of $7.13 per share, and (v) 7,500 ordinary shares issuable upon exercise of outstanding options at a price of $6.34 per share, and (vi) 564 ordinary shares issued upon vesting of outstanding RSUs.

(7) Consists of (i) 3,936 ordinary shares (ii) 2,187 ordinary shares issuable upon exercise of outstanding options at a price of $1.92 per share, and (iii) 15,681 ordinary shares issuable upon exercise of outstanding options at a price of $5.46 per share and (iv) 9,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share, and (v) 5,834 ordinary shares issuable upon exercise of outstanding options at a price of $7.13 per share, and (vi) 7,500 ordinary shares issuable upon exercise of outstanding options at a price of $6.34 per share, and (vii) 564

ordinary shares issued upon vesting of outstanding RSUs.

(8) Consists of (i) 3,936 ordinary shares (ii) 6,406 ordinary shares issuable upon exercise of outstanding options at a price of $1.92 per share, and (iii) 15,681 ordinary shares issuable upon exercise of outstanding options at a price of $5.46 per share and (iv) 9,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share, and (v) 63,126 ordinary shares issuable upon exercise of outstanding options at a price of $7.13 per share, and (vi) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.34 per share, and (vii) 1,189 ordinary shares issued upon vesting of outstanding RSUs.

(9) Consists of (i) 14,949 ordinary shares (ii) 9,375 ordinary shares issuable upon exercise of outstanding options at a price of $7.98 per share, and (iii) 74,003 ordinary shares issuable upon exercise of outstanding options at a price of $7.14 per share and (iv) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.04 per share, and (v) 625 ordinary shares issued upon vesting of outstanding RSUs.

(10) Consists of (i) 10,015 ordinary shares (ii) 6,250 ordinary shares issuable upon exercise of outstanding options at a price of $7.98 per share, and (iii) 14,271 ordinary shares issuable upon exercise of outstanding options at a price of $7.14 per share, and (iv) 7,500 ordinary shares issuable upon exercise of outstanding options at a price of $6.04 per share.

(11) Consists of (i) 10,015 ordinary shares (ii) 3,125 ordinary shares issuable upon exercise of outstanding options at a price of $7.98 per share, and (iii) 6,676 ordinary shares issuable upon exercise of outstanding options at a price of $7.14 per share, and (iv) 3,750 ordinary shares issuable upon exercise of outstanding options at a price of $6.04 per share.

(12) Consists of 18,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share.

(13) Consists of 18,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share.

(14) Consists of 18,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share.

(15) Consists (i) 16,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.88 per share, and (ii) 1,000 ordinary shares issuable upon exercise of outstanding options at a price of $10.80 per share

(16) Consists of (i) 3,936 ordinary shares (ii) 10,813 ordinary shares issuable upon exercise of outstanding options at a price of $1.92 per share, and (iii) 18,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share and (iv) 9,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.77 per share, and (v) 13,373 ordinary shares issuable upon exercise of outstanding options at a price of $7.13 per share, and (vi) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $6.34 per share, and (vii) 564 ordinary shares issued upon vesting of outstanding RSUs.

(17) Consists of 8,000 ordinary shares issuable upon exercise of outstanding options at a price of $11.87 per share.

(18) Consists of 16 persons.

Shelf registration statement

On October 21, 2015, we filed with the SEC a "shelf" registration statement on a Form F-3 for the registration of our ordinary shares that we may, from time to time, offer and sell in one or more offerings with an aggregate offering price of up to $150 million. On September 12, 2016, we filed with the SEC an amendment to the shelf registration statement on a Form F-3/A, which became effective on September 23, 2016. On September 30, 2016, we completed a follow-on offering in which we sold a total of 6,111,959 ordinary shares (including shares that were sold following the exercise of the option granted to the underwriters) for $9.50 per share, and certain selling shareholders sold 300,000 of their ordinary shares at the same price per share.

7.B. Related Party Transactions

For compensation to our directors and officers, see "Item 6.B. Compensation."

Agreements and Arrangements with, and Compensation of, Directors and Executive Officers

Employment agreements

We have entered into written employment agreements with each of our executive officers. These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law. The agreements are terminable by us at will, subject to prior notice, which varies for each individual. Our executive officers will not receive benefits upon termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment. However, all of our executive officers will be entitled to accelerated vesting of their stock options and RSUs in the event of termination without cause, so that all options scheduled to vest after the date of termination will become fully vested upon the effective date of termination.

We have also entered into employment agreements with each of Dr. Dov Tamarkin and Meir Eini, which contain provisions similar to those included in the agreements entered into with our other executive officers, as set out above. However, these agreements allow each of Dr. Tamarkin and Mr. Eini to change their mode of employment and provide us with their management services through companies wholly owned and controlled by them rather than as our direct employees, provided that each of them undertakes to personally perform the management services and carry out the roles and responsibilities of their respective offices on behalf of these companies, as well as hold us harmless and indemnify us for any claim for additional compensation under an employer-employee relationship.

Consulting and option agreements

As of December 31, 2016, our agreement with ZEAS Technology and Science Management Ltd., a company beneficially owned by Dr. Stanley Hirsch, the chairman of our board of directors, remained in effect. The agreement required ZEAS to provide us with various business consulting services through Dr. Hirsch, in consideration for the grant of options under our 2009 Plan, in the number and on the terms set out in the section above titled "Item 7.A. Major Shareholders— (7)." On January 25, 2017, the agreement was terminated by the mutual written consent of both parties.

Indemnification agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by the Israeli Companies Law. We have entered into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent

permitted by Israeli law, including with respect to liabilities resulting from a public offering of our shares, to the extent that such liabilities are not covered by insurance. We have also obtained Directors and Officers insurance for each of our executive officers and directors. For further information, see "Item 6.C. Board Practices—Exculpation, Insurance and Indemnification of Directors and Officers."

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

8.A. Consolidated Statements and Other Financial Information

See "Item 18 – Financial Statements."

Legal proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings. We may become involved in material legal proceedings in the future.

Dividends

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

The Israeli Companies Law imposes further restrictions on our ability to declare and pay dividends. See Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Description of Share Capital—Dividend and Liquidation Rights" for additional information.

Payment of dividends may be subject to Israeli withholding taxes. See "Item 10.E. Taxation" for additional information.

8.B. Significant changes

Except as disclosed elsewhere in this annual report, there have been no other significant changes since December 31, 2016.

ITEM 9. THE OFFER AND LISTING

9.A.4 Offer and Listing Details

Our ordinary shares have been listed on the NASDAQ Global Market under the symbol "FOMX" since September 17, 2014. Prior to that date, there was no public trading market for our ordinary shares. Our initial public offering was priced at $6.00 per share. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on the NASDAQ Global Market:

	Low	High
Annual Information:		
2016	$5.48	$11.26
2015	6.25	14.00
Quarterly Information:		
Fourth Quarter 2016	7.12	11.26
Third Quarter 2016	6.16	10.40
Second Quarter 2016	5.70	7.67
First Quarter 2016	5.48	8.45
Fourth Quarter 2015	6.25	9.50
Monthly Information:		
September 2016	$8.05	$10.40
October 2016	7.78	9.65
November 2016	7.12	9.42
December 2016	8.97	11.26

January 2017	9.58	11.27
February 2017 (through February 20)	9.85	11.11

9.B. Plan of Distribution

Not applicable.

9.C. Market for Ordinary Shares

Our Ordinary Shares have been quoted on the NASDAQ Global Market since September 17, 2014 under the symbol "FOMX."

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share Capital

Not applicable.

10.B. Memorandum and Articles of Association

The information called for by this item has been reported previously in our Registration Statement on Form F-1 as filed under the Securities Act with the SEC on September 3, 2014 and has not changed since, and therefore is incorporated by reference to that Registration Statement.

10.C. Material Contracts

We are currently in the development stage and therefore we have not entered into any agreements, other than in the ordinary course of our business, that we deem material.

10.D. Exchange Controls

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

10.E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership and 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 or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli 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 certain tax benefits, including under the Law for Encouragement of Capital Investments, 5719-1959, to which we may become eligible in the future if we establish a manufacturing facility for our products in Israel. This summary also 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 such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, the appropriate tax authorities or the courts may not accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

General Corporate Tax Structure in Israel

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate in 2016 and thereafter, from 26.5% to 25%.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate will be 24% in 2017 and 23% in 2018 and thereafter.

Taxation of our Shareholders

Capital gains taxes applicable to non-Israeli resident shareholders

A non-Israeli resident who derives capital gains from the sale of our shares that were purchased after the shares were listed for trading on the NASDAQ is exempt from Israeli tax so long as such gains were not attributable to a permanent establishment that the non-resident maintains in Israel. In the case of a shareholder that is a corporation, in order for it to qualify as a non-Israeli resident for these purposes, it must be incorporated in, as well as managed and controlled from, a jurisdiction other than the State of Israel, and persons who are Israeli residents may not either: (i) have a controlling interest (directly or indirectly, alone or together with another, or together with another Israeli resident) exceeding 25% in one or more of the means of control in such corporation or (ii) be the beneficiaries of, or entitled to, 25% or more of the revenues or profits of such corporation, whether directly or indirectly.

Taxation of non-Israeli shareholders on receipt of dividends

Non-Israeli residents are generally subject to Israeli withholding tax on the receipt of dividends paid on our ordinary shares at the rate of 25%, unless relief is provided in a treaty between Israel and the shareholder's country of residence (subject to the receipt of a valid certificate from the Israel Tax Authority, allowing for such reduced withholding tax rate). With respect to a person who is considered a substantial shareholder at the time of receiving the dividend or at any time during the preceding 12 months, subject to the terms of an applicable tax treaty, the applicable withholding tax rate is 30%. Notwithstanding all of the above, an additional 3% tax might be applicable to individual shareholders if certain conditions are met. A person is considered to be a substantial shareholder if it holds, directly or indirectly, alone or together with another affiliated party, 10% or more of a company's means of control, which include, among other things, voting rights, the right to receive profits of the company, the right to receive proceeds upon liquidation and the right to appoint a director.

Under the U.S.-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) is 25%. However, with regard to dividends paid to a U.S. resident corporation which held 10% or more of our outstanding voting rights throughout the tax year in which the dividend was distributed and which maintained its shareholdings at or above such threshold during the entire previous tax year, the maximum rate of withholding tax is generally 12.5%, provided that no more than 25% of our gross income for such preceding year consists of certain types of dividends and interest.

U.S. residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for U.S. federal income tax purposes in the amount of the taxes withheld, subject to detailed limitations under U.S. laws applicable to foreign tax credits.

A non-Israeli resident who receives dividends from which the full amount of tax was withheld according to sections 161, 164, or 170 of the Israeli Tax Ordinance is generally exempt from the obligation to file tax returns in Israel with respect to such income.

In the event we declare a dividend, we may not designate the income that we may distribute in a way that will reduce shareholders' tax liability.

U.S. Federal Income Tax Consequences

The following is a description of the U.S. federal income tax consequences of the ownership and disposition of our ordinary shares. This description does not address tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

·banks, financial institutions or insurance companies;

·real estate investment trusts, regulated investment companies or grantor trusts;

·dealers or traders in securities, commodities or currencies;

· tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the U.S. Internal Revenue Code, or the Code, respectively;

·certain former citizens or long-term residents of the U.S.;

·persons that received our shares as compensation for the performance of services;

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persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;

- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;

- S corporations;

- holders that acquire ordinary shares as a result of holding or owning our preferred shares;

- U.S. Holders (as defined below) whose "functional currency" is not the U.S. Dollar; or holders that own or have owned directly or indirectly 10.0% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the ownership and disposition of our ordinary shares.

This description is based on the Code existing, proposed and temporary U.S. Treasury Regulations and judicial and administrative interpretations thereof, in each case as in effect and available on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. The U.S. Internal Revenue Service, or the IRS, may take a different position concerning the tax consequences of the ownership and disposition of our ordinary shares and such a position may be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of purchasing, owning and disposing of our ordinary shares in their particular circumstances.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

· a citizen or resident of the U.S.;

· a corporation (or other entity treated as a corporation) created or organized in or under the laws of the U.S. or any state thereof, including the District of Columbia;

· an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust if such trust has validly elected to be treated as a U.S. person for U.S. federal income tax purposes or if (1) a court within the U.S. is able to exercise primary supervision over its administration and (2) one or more U.S. persons have the authority to control all of the substantial decisions of such trust.

A "Non-U.S. Holder" is a beneficial owner of our ordinary shares that is neither a U.S. Holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor as to the particular U.S. federal income tax consequences of owning and disposing of our ordinary shares in its particular circumstance.

Unless otherwise indicated, this discussion assumes that the Company is not, and will not become, a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes. See "Item 10.E. Taxation—U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Considerations" below.

You should consult your tax advisor with respect to the U.S. federal, state, local and foreign tax consequences of owning and disposing of our ordinary shares.

Distributions

The gross amount of any distribution made to you with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom will generally be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. However, this will not apply to certain distributions, if any, of our ordinary shares that are distributed pro rata to all our shareholders. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of your adjusted tax basis in our ordinary shares and thereafter as either long-term or short-term capital gain depending upon whether you have our ordinary shares for more than one year as of the time such distribution is received. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles. Therefore you should expect that the entire amount of any distribution will generally be reported as ordinary dividend income to you. Non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year), provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. Moreover, such lower rate of taxation shall not apply if the Company is a PFIC for the taxable year in which it pays a dividend, or was a PFIC for the preceding taxable year. Such dividends will not be eligible for the dividends received deduction generally allowed to corporate holders.

Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute

generally should generally constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit. Subject to certain exceptions, dividends paid to you with respect to our ordinary shares will be treated as foreign source income, which may be relevant in calculating your foreign tax credit limitation. However, for periods in which we are a "United Stated-owned foreign corporation," a portion of dividends paid by us may be treated as U.S. source solely for purposes of the foreign tax credit. We would be treated as a U.S. owned foreign corporation if 50% or more of the total value or total voting power of our stock is owned, directly, indirectly or by attribution, by U.S. persons. To the extent any portion of our dividends is treated as U.S. source income pursuant to this rule, the ability of a holder to claim a foreign tax credit for any Israeli withholding taxes payable in respect of our dividends may be limited. U.S. Holders should consult their own tax advisors about the effect of, and any exception available to, the special sourcing rule described in this paragraph.

Dividends paid in NIS will be included in income in a U.S. dollar amount calculated by reference to the prevailing spot market exchange rate in effect on the day the dividends are received by you, regardless of whether the NIS are converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of NIS into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in NIS are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

Sale, exchange or other disposition of ordinary shares

You will generally recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on such sale, exchange or other disposition and your adjusted tax basis in our ordinary shares, and such gain or loss will be capital gain or loss. If Israeli tax is imposed on the sale, exchange or other disposition of our ordinary shares, your amount realized will include the gross amount of the proceeds of the deposits before deduction of the Israeli tax. The adjusted tax basis in an ordinary share will generally be equal to the cost of such ordinary share. If you are a non-corporate holder, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period for such ordinary shares exceeds one year. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code.

Any such gain or loss that a holder recognizes will generally be treated as U.S. source income or loss for foreign tax credit limitation purposes. Because gain from the sale or other disposition of our ordinary shares will be so treated as U.S. source income; and you may use foreign tax credits to offset only the portion of U.S. federal income tax liability that is attributed to foreign source income; you may be unable to claim a foreign tax credit with respect to the Israeli tax, if any, on gains. You should consult your tax advisor as to whether the Israeli tax on gains may be creditable against your U.S. federal income tax on foreign-source income from other sources.

A Non-U.S. Holder, will generally not be subject to U.S. federal income or withholding tax on any gain realized on the sale or exchange of such ordinary shares unless:

- such gain is effectively connected with your conduct of a trade or business in the U.S. (or, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that such holder maintains in the U.S.); or

- you are an individual and have been present in the U.S. for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Passive foreign investment company considerations

If we were to be classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or

- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. For publicly traded corporations, the PFIC asset test described above is applied using the fair market value of the non-U.S. corporation's

assets. For purposes of a the PFIC asset test, a publicly traded non-U.S. corporation may treat the aggregate fair market value of its assets as being equal to the sum of the aggregate value of its outstanding stock, or Market Capitalization, and the total amount of its liabilities. We intend to take the position that the excess of a non-U.S. corporation's Market Capitalization plus liabilities over the book value of all of its assets may generally be treated as a non-passive asset to the extent attributable to the non-passive activities of such corporation. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we will generally continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

Based on certain estimates of our gross income and gross assets and the nature of our business, we believe that we were not classified as a PFIC for the taxable year ended December 31, 2016, and do not anticipate being classified as a PFIC for the taxable year ending December 31, 2017. However, because PFIC status is based on our income, assets and activities for the entire taxable year and our Market Capitalization, it is not possible to determine whether we will be characterized as a PFIC for the 2016 taxable year until after the close of the year. Moreover, we must determine our PFIC status annually based on tests which are factual in nature, and our status in future years will depend on our income, assets, activities and our Market Capitalization in those years. We may be considered a PFIC for any taxable year.

If we were a PFIC, then unless you make one of the elections described below, a special tax regime will apply to both (i) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (ii) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax, at the your regular ordinary income rate for the current year and would not be subject to the interest change discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares.

If a U.S. Holder makes the mark-to-market election, then, in lieu of being subject to the tax and interest charge rules discussed above, the U.S. Holder will generally recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, such holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ordinary shares, are traded on a qualified exchange on at least 15 days during each calendar quarter. The NASDAQ Global Market is a qualified exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the tax and interest charge rules discussed above with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including stock in any of the Company's subsidiaries that are treated as PFICs. If a U.S. Holder makes a mark-to market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, such holder will generally be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. Holder's federal income tax return for that year.

You should consult your tax advisors regarding whether we are a PFIC and the potential application of the PFIC rules.

Medicare tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Foreign asset reporting

Certain Holders who are individuals are required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to ownership and disposition of our ordinary shares. You should consult your tax advisor concerning the tax consequences of your particular situation.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We are subject to certain of the information reporting requirements of the Exchange Act, or the Exchange Act. As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act, with respect to their purchase and sale of our shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

You may read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, D.C. 20549. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of this website is http://www.sec.gov. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

10.I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates. Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows.

Foreign currency exchange risk

The U.S. dollar is our functional and reporting currency. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in Israeli shekels, accounting for 21%, 32% and 73% of our expenses in the years ended December 31, 2016, 2015 and 2014, respectively, almost all our revenues were generated under agreements denominated in U.S. dollars and our proceeds from our public offerings, share issuance and convertible loan agreements, which are the main source of our financing, are denominated in U.S. dollars. Furthermore, while we anticipate that a portion of our expenses, principally salaries and related personnel expenses in Israel, will continue to

be denominated in shekels, we expect to incur an increasing amount of expenses in U.S. dollars as we expand our operations in the U.S. We also have expenses, although to a much lesser extent, in other non-dollar currencies, in particular the Euro. Moreover, for the next few years we expect that the substantial majority of our revenues, if any, will be denominated in U.S. dollars from the sale of FMX101 and potentially other product candidates in the U.S. Having the substantial majority of our revenues denominated in U.S. dollars while having a substantial portion of our expenses denominated in Israeli shekels and other non-U.S. currencies exposes us to risk, associated with exchange rate fluctuations vis-à-vis the U.S. dollar. See "Item 3.D. Risk Factors—Exchange rate fluctuations between the U.S. dollar and the Israeli shekel may negatively affect our earnings."

A devaluation of the shekel in relation to the U.S. dollar has the effect of reducing the U.S. dollar amount of our expenses or payables that are payable in shekels, unless those expenses or payables are linked to the U.S. dollar. Conversely, any appreciation of the shekel in relation to the U.S. dollar has the effect of increasing the U.S. dollar value of our unlinked shekel expenses, which would have a negative impact on our profit margins. In 2016, the value of the shekel appreciated in relation to the U.S. dollar by -1.5%, the effect of which was compounded by deflation in Israel at a rate of approximately -0.2%. In 2016, the value of the shekel depreciated in relation to the U.S. dollar by approximately 0.3%, the effect of which was set-off by deflation in Israel at the rate of approximately -1.0%.

Because exchange rates between the U.S. dollar and the shekel (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency re-measurements are reported in our statements of operations.

The following table presents information about the changes in the exchange rates of the shekel against the U.S. dollar:

	Shekel against the U.S. dollar (%)
2015	(0.3)%
2016	1.5 %

We will continue to monitor exposure to currency fluctuations. Since February 2015 we engage in currency hedging activities in order to reduce our exposure to currency fluctuations. Instruments that are used to hedge future risks may include foreign currency forward, swap contracts and options. These instruments may be used to selectively manage risks, but we may not be fully protected against material foreign currency fluctuations.

Inflation-related risks

We do not believe that the rate of inflation in Israel has had a material impact on our business to date, however, our costs in Israel will increase if inflation in Israel exceeds the devaluation of the shekel against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

As of December 31, 2016, we do not have any market risk sensitive instruments.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

12.A-D.2.

Not applicable.

12D.3-4.

The Company does not have any outstanding American Depositary Shares or American Depositary Receipts.

PART TWO

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2016, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) 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 Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company's executive and 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions 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 of 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, 2016. 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 our assessment, management believes that as of December 31, 2016 our internal control over financial reporting is effective based on this criteria.

(c) Attestation Report of the Registered Public Accounting Firm

See statement in Section B above. As an "emerging growth company," as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of SOX (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. Audit Committee Financial Expert

We do not currently have an audit committee financial expert as such term is defined by the SEC. However, our board of directors has determined in its business judgment that our existing committee members have the ability to oversee our financial statements based on their extensive business backgrounds and that Stanley Stern has "financial sophistication" under the NASDAQ Stock Market rules. For Mr. Stern's qualifications please refer to "Item 6.A. Directors and Senior Management."

ITEM 16B. CODE OF ETHICS

Code of Business Conduct and Ethics

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

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Kesselman & Kesselman (a member firm of Pricewaterhouse Coopers International Limited, or PwC), has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2016 and 2015.

The following table provides information regarding fees paid by us to PwC for all services, for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
Audit fees [1]	$182	$193
Tax fees[2]	-	9
Total fees	$182	$202

(1) Includes professional services rendered in connection with the audit of our annual financial statements, the review of our interim financial statements, fees for the 2016 and 2015 follow-on offerings and shelf registration statements.
(2) Tax consulting services.

Pre-Approval of Auditors' Compensation

Our audit committee is responsible for pre-approving audit and non-audit services provided to us by our independent registered public accounting firm. All of the non-audit services provided to us by the independent auditors in following the formation of our audit committee were pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

None.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

ITEM 16G. CORPORATE GOVERNANCE

Home Country Practice Exemptions

Companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies with shares listed on the NASDAQ Global Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee and an internal auditor. This is the case even if the shares of such companies are not listed on the Tel Aviv Stock Exchange and are listed exclusively on a non-Israeli stock exchange, although such companies are allowed to opt-out of several of these corporate governance requirements under certain conditions. These requirements are in addition to the corporate governance requirements imposed by the NASDAQ Stock Market rules and other applicable provisions of U.S. securities laws to which we are subject as a foreign private issuer. Under the NASDAQ Stock Market rules, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the NASDAQ Stock Market rules, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

We rely on this "home country practice exemption" with respect to, among others, the following requirements:

- Reporting requirements. We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders will be exempt from the requirements to report equity holdings contained in Section 16 of the Exchange Act.

- Requirement to have a majority of independent directors. Under the rules of the NASDAQ, a U.S. domestic listed company generally must have a majority of independent directors on its board. Under the Israeli Companies Law and the regulations promulgated thereunder, we may opt-out of certain Israeli requirements related to the obligation to appoint external directors, within the meaning of the Companies Law, as we have done. See "Item 6.C. Board Practices—Board of Directors."

- Nomination of directors. With the exception directors elected by our board of directors due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following one year from his or her election. See "—Board Practices—Board of Directors." The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself, in accordance with the provisions of our amended and restated articles of association and the Israeli Companies Law. Nominations need not be made by a nominating committee of our board of directors consisting solely of independent directors or otherwise, as required under the NASDAQ Stock Market rules.

- Compensation of officers. Israeli law and our amended and restated articles of association do not require that the independent members of our Board of Directors (or a compensation committee composed solely of independent members of our Board of Directors) determine an executive officer's compensation, as is generally required under the Listing Rules of the NASDAQ Stock Market with respect to the Chief Executive Officer and all other executive officers. Rather, compensation of officers requires approval first by the company's compensation committee, then by the company's board of directors. If such compensation arrangement is inconsistent with the company's stated compensation policy, or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is further subject to a Special Majority Approval for Compensation. Compensation is either consistent with our office holder compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations stated in the Israeli Companies Law. For additional information see "Item 6.B. Compensation."

- Quorum. As permitted under the Israeli Companies Law pursuant to our amended and restated articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Israeli Companies Law, who hold at least 25% of the voting power of our shares (and in an adjourned meeting, with some exceptions, at least two shareholders), instead of 33 % of the issued share capital required under the NASDAQ Stock Market rules.

- Shareholder approval. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Israeli Companies Law, rather than seeking approval for corporation actions in accordance with NASDAQ Listing Rule 5635. In particular, under this NASDAQ rule, shareholder approval is generally required for: (i) an acquisition of shares 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 (including 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 Israeli Companies Law, shareholder approval is required for, among other things: (a) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (b) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described in the Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Management—Approval of Related Party Transactions Under Israeli Law—Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," and (c) terms of employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative, which require the special approval described Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Management—Approval of Related Party Transactions Under Israeli Law— Disclosure of personal interests of a controlling shareholder and approval of transactions." In addition, under the Israeli Companies Law, a merger requires approval of the shareholders of each of the merging companies.

Among the matters for which we do not seek shareholder approval, in reliance on Israeli law and contrary to NASDAQ Rule 5635, is the material increase of the number of shares reserved for grant to our employees, officers and service providers under our share incentive plans, and registered by our filings on Form S-8.

We otherwise generally intend comply with the rules generally applicable to U.S. domestic companies listed on the NASDAQ Global Market. We may in the future decide to use the foreign private issuer opt-out with respect to some or all of the other NASDAQ Stock Market rules.

Fiduciary Duties of Directors and Executive Officers

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

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

The duty of care includes a duty to use reasonable means to obtain:

- 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 any such action.

The duty of loyalty 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 and Approval of Certain Transactions

The Israeli Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an action or transaction of a company, including a personal interest of such person's related party or of a corporate body in which such person or a related party of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the company.

A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

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

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

·a transaction that is not on market terms; or

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

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the company's articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of his or her duty of loyalty. However, a company may not approve a transaction or action that is not in the company's interest or that is not performed by the office holder in good faith.

An extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors.

The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors. If such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy, or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is further subject to a Special Majority Approval for Compensation. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the compensation committee, board of directors and shareholders by ordinary majority, in that order, and under certain circumstances, a Special Majority Approval for 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 the chairman of the relevant 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. If a majority of the members of the audit committee or 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 or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

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 shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated.

The approval of the audit committee, the board of directors and the shareholders of the company, in that order, is required for (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (iii) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (iv) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder. In addition, the shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approves the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

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

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Israeli Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors. Under these regulations, a shareholder holding at least 1% of the issued share capital of the company may require, within 14 days of the publication of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

Shareholder Duties

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

·the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include a controlling shareholder, a shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and a shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Israeli Companies Law does not define the substance of the 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.

Anti-Takeover Measures under Israeli Law

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

Acquisitions under Israeli Law

Full tender offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, 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 also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of 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, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether 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 offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class.

Special tender offer

The Israeli 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 requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Israeli Companies Law provides that an acquisition of shares in a public company must be made by means of a 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, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) the offeror acquired shares representing at least 5% of the voting power in the company and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares held by shareholders who object to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by a majority vote of each party's shareholders. In the case of the target company, approval of the merger further requires a majority vote of each class of its shares.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the meeting of shareholders that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same Special Majority approval that governs all extraordinary transactions with controlling shareholders (as described Registration Statement on Form F-1 as filed under the Securities Act with the SEC on August 13, 2014, under "Management—Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions").

If the transaction would have been approved by the shareholders of a merging company if it weren't for the need for separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the respective values assigned to each of the parties to the merger and the consideration offered to the shareholders of the target company.

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 merging entities, and may further give instructions to secure the rights of creditors.

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

Borrowing Powers

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

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART THREE

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The following consolidated financial statements, and the related notes thereto, and the Reports of Independent Public Accountants are filed as a part of this annual report.

ITEM 19. EXHIBITS

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1	Amended and Restated Articles of Association of the Company*
4.1	2009 Israeli Share Option Plan*
4.2	2015 Israeli Share Incentive Plan**
4.3	Summary English Translation of Lease Agreement, dated as of May 7, 2008, as amended, by and between the Registrant and Gav Yam Real Estate Ltd**
4.4	Form of indemnification agreement by and between the Registrant and each of its directors and executive officers*
4.5	Employment Agreement, dated as of August 22, 2014, between the Registrant and Dr. Dov Tamarkin*
4.6	Employment Agreement, dated as of August 22, 2014, between the Registrant and Meir Eini*
4.7	Foamix Pharmaceuticals Ltd. Compensation Policy for Officers and Directors****
12.1	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
12.2	Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
13.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350
13.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350
15.1	Consent of Kesselman & Kesselman, independent registered public accounting firm

* Filed as an exhibit to Form F-1/A filed by the Company on September 3, 2014 (File No. 333-198123) and incorporated herein by reference.

** Filed as an exhibit to Form F-3 filed by the Company on October 21, 2015 (File No. 333-207546) and incorporated herein by reference.

*** Filed as an exhibit to Form F-3/A filed by the Company on September 12, 2016 (File No. 333-207546) and incorporated herein by reference.

**** Filed as an exhibit to Form 6-K/A filed by the Company on May 20, 2015.

The following materials from our Annual Report on Form 20-F for the year ended December 31, 2016 formatted in XBRL (Extensible Business Reporting Language) are furnished herewith: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehensive Loss, (iii) the Consolidated Statements of Changes in Shareholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

SIGNATURES

Foamix Pharmaceuticals Ltd. 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.

FOAMIX
PHARMACEUTICALS
LTD.

By: /s/ Dov Tamarkin
Dr. Dov Tamarkin
Chief Executive Officer

Date: February 21, 2017

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2016

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the shareholders of
FOAMIX PHARMACEUTICALS LTD.

We have audited the accompanying consolidated balance sheets of Foamix Pharmaceuticals Ltd. and its subsidiary as of December 31, 2016 and 2015 and the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Company's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2016 and 2015 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

Tel-Aviv, Israel /s/ Kesselman & Kesselman
February 21, 2017 Certified Public Accountants (lsr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31	
	2016	2015
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$31,190	$18,795
Restricted cash	250	-
Short term bank deposits	38,351	13,107
Investment in marketable securities (Note 4)	43,275	23,693
Restricted investment in marketable securities (Note 4)	261	769
Accounts receivable:		
Trade	3,236	314
Other (Note 11)	438	471
TOTAL CURRENT ASSETS	117,001	57,149
NON-CURRENT ASSETS:		
Investment in marketable securities (Note 4)	17,532	32,285
Restricted investment in marketable securities (Note 4)	129	-
Investment in long term bank deposits	-	15,130
Property and equipment, net (Note 5)	938	646
Other	35	35
TOTAL NON-CURRENT ASSETS	18,634	48,096
TOTAL ASSETS	$135,635	$105,245

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

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31	
	2016	2015
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Current maturities of bank borrowing (Note 8c)	$20	$31
Accounts payable and accruals:		
Trade	2,267	1,353
Deferred revenues	-	29
Other (Note 11)	2,984	2,169
Loan from the BIRD foundation (Note 8a)	-	476
TOTAL CURRENT LIABILITIES	5,271	4,058
LONG-TERM LIABILITIES:		
Bank borrowing (Note 8c)	-	20
Liability for employee severance benefits (Note 6)	379	365
TOTAL LONG-TERM LIABILITIES	379	385
TOTAL LIABILITIES	5,650	4,443
COMMITMENTS (Note 7)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 50,000,000 Ordinary Shares as of December 31, 2016 and December 31, 2015; issued and outstanding: 37,167,791 and 30,639,134 Ordinary Shares as of December 31, 2016 and December 31, 2015, respectively	1,561	1,284
Additional paid-in capital	204,052	145,878
Accumulated deficit	(75,566)	(46,230)
Accumulated other comprehensive loss	(62)	(130)
TOTAL SHAREHOLDERS' EQUITY	129,985	100,802
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$135,635	$105,245

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

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Year ended December 31		
	2016	2015	2014
REVENUES (Note 11)	$5,527	$849	$5,414
COST OF REVENUES	59	70	527
GROSS PROFIT	5,468	779	4,887
OPERATING EXPENSES:			
Research and development	25,897	10,680	3,557
Selling, general and administrative	9,221	7,029	2,964
TOTAL OPERATING EXPENSES	35,118	17,709	6,521
OPERATING LOSS	29,650	16,930	1,634
FINANCE EXPENSES (INCOME), net (Note 11)	(701)	(452)	9,844
LOSS BEFORE INCOME TAX	28,949	16,478	11,478
INCOME TAX (Note 10)	387	39	6
NET LOSS FOR THE YEAR	$29,336	$16,517	$11,484
LOSS PER SHARE BASIC AND DILUTED	$0.91	$0.58	$0.79
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	32,263	28,229	14,512

The accompanying notes are an integral part of these consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. dollars in thousands)

	Year ended December 31		
	2016	2015	2014
NET LOSS	$29,336	$16,517	$11,484
OTHER COMPREHENSIVE LOSS (INCOME):			
Net unrealized losses (gains) from marketable securities	(65)	103	68
Gains (losses) on marketable securities reclassified into net loss	4	(57)	11
Net unrealized losses (gains) on derivative financial instruments	(20)	5	-
Gains on derivative financial instruments reclassified into net loss	13	-	-
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	(68)	51	79
TOTAL COMPREHENSIVE LOSS	$29,268	$16,568	$11,563

The accompanying notes are an integral part of these financial statements

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share data)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Number of shares	Amounts	Amounts			
BALANCE AT JANUARY 1, 2014	11,408,490	$ 471	$ 14,176	$ (18,229)	$ -	$ (3,582)
CHANGES DURING 2014:						
Comprehensive loss	-	-	-	(11,484)	(79)	(11,563)
Capital contribution (Note 8b)	-	-	686	-	-	686
Conversion of preferred A shares into Ordinary Share (Note 9)	3,367,244	147	13,291	-	-	13,438
Conversion of warrants from preferred A warrants to Ordinary Share warrants (Note 9d)	-	-	8,494	-	-	8,494
Issuance of Ordinary Shares through an initial public offering, net of $4.9 million issuance costs (Note 9c)	7,668,200	336	40,756	-	-	41,092
Share-based compensation (Note 9f)	-	-	197	-	-	197
BALANCE AT DECEMBER 31, 2014	22,443,934	954	77,600	(29,713)	(79)	48,762
CHANGES DURING 2015:						
Comprehensive loss	-	-	-	(16,517)	(51)	(16,568)
Issuance of Ordinary Shares through a public offering, net of $4.8 million issuance costs (Note 9c)	7,419,353	298	63,904	-	-	64,202
Exercise of warrants (Note 9e)	546,322	23	2,262	-	-	2,285
Exercise of options and restricted share units (Note 9f)	229,525	9	335	-	-	344
Share-based compensation (Note 9f)	-	-	1,777	-	-	1,777
BALANCE AT DECEMBER 31, 2015	30,639,134	1,284	145,878	(46,230)	(130)	100,802
CHANGES DURING 2016:						
Comprehensive income (loss)	-	-	-	(29,336)	68	(29,268)
Issuance of Ordinary Shares through a public offering, net of $3.9 million issuance costs (Note 9c)	6,111,959	260	53,872	-	-	54,132
Exercise of warrants (Note 9e)	257,137	10	1,285	-	-	1,295
Exercise of options and restricted share units (Note 9f)	159,561	7	105	-	-	112
Share-based compensation (Note 9f)	-	-	2,912			2,912
BALANCE AT DECEMBER 31, 2016	37,167,791	$ 1,561	$ 204,052	$ (75,566)	$ (62)	$ 129,985

The accompanying notes are an integral part of these financial statements

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31		
	2016	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net Loss	$(29,336)	$(16,517)	$(11,484)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	143	87	33
Loss from disposal of fixed assets	16	15	-
Changes in marketable securities and bank deposits, net	91	57	550
Changes in accrued liability for employee severance benefits, net of retirement fund profit	14	35	81
Share-based compensation	2,912	1,777	197
Non-cash finance expenses (income), net	(1)	(8)	9,925
Changes in operating asset and liabilities:			
Decrease (increase) in trade and other receivable	(2,889)	140	(338)
Increase in other non-current assets	-	(1)	(24)
Increase in accounts payable and accruals	1,680	1,917	346
Net cash used in operating activities	(27,370)	(12,498)	(714)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(424)	(500)	(219)
Investment in bank deposits	(23,000)	(28,000)	-
Investment in marketable securities	(31,700)	(72,518)	(11,107)
Proceeds from sale and maturity of marketable securities and bank deposits	40,106	22,502	3,977
Net cash used in investing activities	(15,018)	(78,516)	(7,349)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares through public offerings, net of issuance costs	54,132	64,202	41,092
Proceeds from issuance of Preferred A shares and warrants, net of issuance costs	-	-	8,157
Proceeds from exercise of warrants	1,295	2,285	-
Proceeds from exercise of options	112	344	-
Payments in respect of BIRD loan	(476)	-	-
Bank borrowings	-	-	102
Payments in respect of bank borrowings	(32)	(30)	(12)
Net cash provided by financing activities	55,031	66,801	49,339
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	12,643	(24,213)	41,276
EFFECT OF EXCHANGE RATE ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2	*-	(15)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD	18,795	43,008	1,747
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIOD	$31,440	$18,795	$43,008

Cash and cash equivalents	$31,190	$18,795	$43,008
Restricted cash	250	-	-
TOTAL CASH, CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	$31,440	$18,795	$43,008
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS -			
Cashless exercise of warrants	-	4	-
Conversion of convertible loans into Preferred A Shares and warrants	-	-	8,096
Conversion of Preferred A Shares into Ordinary Shares	-	-	13,438
Conversion of warrants from preferred A warrants to Ordinary Share warrants	-	-	8,494
Property and equipment purchases included in accounts payable and accruals	27	-	-
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for taxes	163	16	-
Interest received	1,015	921	-
Interest paid	239	-	-

* Represents an amount less than $1.

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

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share amounts)

NOTE 1 - NATURE OF OPERATIONS

Foamix Pharmaceuticals Ltd. (hereinafter “Foamix”) is an Israeli company incorporated in 2003. Foamix’s shares are publicly traded on the NASDAQ under the symbol “FOMX”, since its initial public offering (“IPO”) in September, 2014.

Foamix is a clinical-stage specialty pharmaceutical company operating in one segment - the development and commercialization of foam-based formulations, using its proprietary technology, which includes its foam platforms. Foamix develops its own product candidates, mainly for the treatment of moderate-to-severe acne, the treatment of moderate-to-severe papulo-pustular rosacea and other skin conditions. It also licenses its technology under development and licensing agreements to various pharmaceutical companies for development of certain products combining Foamix's foam technology with the licensee’s proprietary drugs.

In May 2014, Foamix incorporated a wholly-owned subsidiary in the United States of America - Foamix Pharmaceuticals Inc. ("the subsidiary"). The subsidiary was incorporated to assist Foamix with regard to marketing, regulatory affairs and business development relating its products and technology.

Since incorporation through December 31, 2016, Foamix and its subsidiary (hereinafter “the Company”) has incurred losses and negative cash flows from operations mainly attributable to its development efforts and has an accumulated deficit of $75,566. The Company has financed its operations mainly through private and public financing rounds, convertible loans, royalties and payments received under development and licensing agreements. The Company's cash, cash equivalents, deposits and marketable securities as of December 31, 2016, will allow the Company to fund its operating plan through at least the next 12 months. However, the Company expects to continue to incur significant research and development and other expenses related to its ongoing operations and in order to continue its future operations, the Company will need to obtain additional funding until becoming profitable. If the Company is unable to obtain such funding it will need to curtail or cease operations.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of presentation

The Company’s financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”).

b. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

c. Functional currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of Foamix and the subsidiary are conducted. Almost all Company revenues and operational expenses are in dollars and the Company's financing has been provided in dollars. Accordingly, the functional currency of the Company is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (i) for transactions - exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) - historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

d. Principles of consolidation

The consolidated financial statements include the accounts of Foamix and its subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

e. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

f. Bank deposits

Bank deposits with original maturity dates of more than three months but less than one year are included in short-term deposits. Bank deposits with maturity of more than one year are considered long-term. The interest rates on the Company's deposits range between 1.3%-1.6%. The fair value of bank deposits approximates the carrying value since they bear interest at rates close to the prevailing market rates.

g. Marketable securities

The Company invests in debt and equity securities classified as available for sale in accordance with ASC 320, Investments - Debt and Equity Securities.

Management determines the appropriate classification of its investments in securities at the time of purchase and reevaluates such determinations at each balance sheet date. Classifications of debt securities in the balance sheet are determined based on the maturity date of the securities.

Unrealized gains of available for sale securities, net of taxes, are reflected in other comprehensive income (loss). Unrealized losses considered to be temporary are reflected in other comprehensive income (loss); unrealized losses that are considered to be other-than-temporary are charged to income as an impairment charge. Realized gains and

losses for both debt and equity securities are included in financial expense (income), net.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

For equity securities, the Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in financial expense, net, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in other comprehensive income or loss.

h. Derivatives

The Company purchases foreign exchange derivative financial instruments (written and purchased currency options). The transactions are designed to hedge the Company's currency exposure.

The Company recognizes all derivatives as either assets or liabilities in the consolidated balance sheet at their fair value. Changes in the fair value of derivatives that are highly effective and designated as cash flow hedges are reported as a component of other comprehensive income or loss and reclassified into earnings in the same line-item associated with the forecasted transaction and in the same periods during which the hedged transaction impacts earnings.

For derivatives that qualify for hedge accounting, the cash flows associated with these derivatives are reported in the consolidated statements of cash flows consistently with the classification of cash flows from the underlying hedged items that these derivatives are hedging.

i. Property and equipment:

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated by the straight-line method on the basis of their estimated useful life.

Annual rates of depreciation are as follows:

	%
Computers	15-33 (mainly 33)
Laboratory equipment	7-20
Office furniture and equipment	7-15
Vehicles	15

Leasehold improvements are amortized by the straight-line method over the expected lease term, which is shorter than the estimated useful life of the improvements.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair value measure.

For the three years ended December 31, 2016, the Company did not recognize an impairment loss for its long-lived assets.

k. Allowance for doubtful accounts

The Company performs ongoing credit evaluations to estimate the need for maintaining reserves for potential credit losses. An allowance for doubtful accounts is recognized on a specific basis with respect to those amounts that the Company has determined to be doubtful of collection. No allowance for doubtful accounts was recorded in the years ended December 31, 2016, December 31, 2015 and December 31, 2014.

l. Contingencies

Certain conditions may exist as of the date of the financial statements, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company’s management assesses such contingent liabilities and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company’s management evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought.

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company’s financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material are disclosed.

Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantees are disclosed.

m. Share-based compensation

The Company accounts for employees’ and directors’ share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. The Company estimates forfeitures based on historical experience and anticipated future conditions.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the straight-line method based on the multiple-option award approach.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2−SIGNIFICANT ACCOUNTING POLICIES (continued):

When options and restricted share units (hereinafter "RSUs") are granted as consideration for services provided by consultants and other non-employees, the grant is accounted for based on the fair value of the consideration received or the fair value of the awards issued, whichever is more reliably measurable. The fair value of the awards granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

n. Revenue recognition

The Company's revenues are derived from development and license agreements for development of products combining the Company's foam technology with a drug selected by the licensee.

The significant deliverables in the agreements between the Company and its licensees are the obligation of the Company to provide development services and the grant of an exclusive license to the specific product developed.

These deliverables are combined into one single unit of accounting for revenue recognition purposes since:

· Each element does not have value on a stand-alone basis.

· In order to develop the combined formulation in the licensed product, the use of the Company's propriety technology is required. Therefore, the Company is the only party capable of performing the level and type of development services required under the agreement.

The Company's development and license agreements entitle the Company to:

· Development payments, including upfront payments, cost reimbursements and payments contingent only upon passage of time (together - "Development Service Payments").

· Payments contingent solely upon performance or achievement of clinical results by the Company's licensees ("Contingent Payments").

· Royalties, calculated as a percentage of sales of the developed products made by the Company's licensees.

Revenues from Development Service Payments under development and license agreements are recognized as the services are provided. When the Company receives a portion of the Development Service Payment before performance of such services, these advances are recorded as deferred revenues and recognized as revenues as services are performed.

Contingent Payments are recognized when the licensee's performance or achievement event occurs.

Royalties are recognized when subsequent sales are made by the licensees.

o. Research and development costs

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

p. Income taxes:

1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. Given the Company's losses, the Company has provided a full valuation allowance with respect to its deferred tax assets.

2) Uncertainty in income tax

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

q. Loss per share

Net loss per share, basic and diluted, is computed on the basis of the net loss for the year divided by the weighted average number of common shares outstanding during the year. Diluted net loss per share is based upon the weighted average number of common shares and of common shares equivalents outstanding when dilutive. Common share equivalents include outstanding stock options and warrants which are included under the treasury share method when dilutive.

The following share options, RSUs and warrants were excluded from the calculation of diluted net loss per ordinary share because their effect would have been anti-dilutive for the periods presented (share data):

	Year ended December 31		
	2016	2015	2014
Outstanding share options and RSUs	2,698,875	2,124,951	1,171,125
Warrants	1,807,800	2,064,937	2,716,956

r. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

s. Concentration of credit risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, restricted cash, bank deposits, marketable securities and certain receivables. The Company deposits cash and cash equivalents with highly rated financial institutions and, as a matter of policy, limits the amounts of credit exposure to any single financial institution. In addition, all marketable securities carry a high rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

t. Comprehensive loss

Comprehensive loss includes, in addition to net loss, unrealized holding gains and losses on available-for-sale securities and derivative instruments designated as cash flow hedge (net of related taxes where applicable).

Reclassification adjustments for gain or loss of available for sales securities are included in finance expenses net in the statement of income.

u. Newly issued and recently adopted accounting pronouncements:

Accounting pronouncements adopted in 2016:

1) In November 2016, the FASB issued ASU 2016-18, “Statement of Cash Flows (Topic 230) Restricted Cash”. The new guidance requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include restricted cash and restricted cash equivalents. If restricted cash is presented separately from cash and cash equivalents on the balance sheet, companies will be required to reconcile the amounts presented on the statement of cash flows to the amounts on the balance sheet. Companies will also need to disclose information about the nature of the restrictions. The guidance is effective for annual an interim reporting periods beginning after December 15, 2017, and early adoption is permitted. The Company has chosen to adopt this guidance starting from the year ended December 31, 2016.

Accounting pronouncements that are not yet effective and have not been early adopted by the Company:

1) In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which impacts virtually all aspects of an entity’s revenue recognition. The core principle of Topic 606 is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In July 2015, the FASB deferred the effective date of the standard by one year which results in the new standard being effective for

the Company at the beginning of its first quarter of fiscal year 2018. In addition, during March, April and May 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing and ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, respectively, which clarified the guidance on certain items such as reporting revenue as a principal versus agent, identifying performance obligations, accounting for intellectual property licenses, assessing collectability and presentation of sales taxes. The Company is currently evaluating the impact of this new standard, however it is not expected to have a material impact on the Company’s consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2) In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments—Overall (Subtopic 825-10)." This standard makes several modifications to Subtopic 825-10 including the elimination of the available-for-sale classification of equity investments, and requires equity investments with readily determinable fair values to be measured at fair value with changes in fair value recognized in net income. It is effective for interim and annual periods beginning after December 15, 2017. The Company is currently evaluating the impact of the amended guidance on its consolidated financial statements.

3) In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

4) In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718). ASU No. 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted but all of the guidance must be adopted in the same period. The adoption of this standard is not expected to have a material impact on the Company’s consolidated financial statements.

5) In June 2016, the FASB issued ASU No. 2016-13, “Measurement of Credit Losses on Financial Instruments.” This ASU significantly changes how entities will measure credit losses for most financial assets and certain other instruments that aren’t measured at fair value through net income. In issuing the standard, the FASB is responding to criticism that today’s guidance delays recognition of credit losses. The standard will replace today’s “incurred loss” approach with an “expected loss” model. The new model, referred to as the current expected credit loss (“CECL”) model, will apply to: (1) financial assets subject to credit losses and measured at amortized cost, and (2) certain off-balance sheet credit exposures. This includes, but is not limited to, loans, leases, held-to-maturity securities, loan commitments, and financial guarantees. The CECL model does not apply to available-for-sale (“AFS”) debt securities. For AFS debt securities with unrealized losses, entities will measure credit losses in a manner similar to what they do today, except that the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. As a result, entities will recognize improvements to estimated credit losses immediately in earnings rather than as interest income over time, as they do today. The ASU also simplifies the accounting model for purchased credit-impaired debt securities and loans. ASU 2016-13 also expands the disclosure requirements regarding an entity’s assumptions, models, and methods for estimating the allowance for loan and lease losses. In addition, entities will need to disclose the amortized cost balance for each class of financial asset by credit quality indicator, disaggregated by the year of origination. ASU No. 2016-13 is effective for interim and annual reporting periods beginning after December 15, 2019; early adoption is permitted for interim and annual reporting periods beginning after

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

December 15, 2018. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective (i.e., modified retrospective approach). The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial statements.

6) In August 2016, the FASB issued ASU No. 2016-15 "Statement of Cash Flows Topic 230: Classification of Certain Cash Receipts and Cash Payments." ASU No. 2016-15 issued guidance to clarify how certain cash receipts and cash payments should be presented in the statement of cash flows. ASU 2014-15 is effective for annual and interim reporting periods beginning on or after December 15, 2016, and early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

NOTE 3 - FAIR VALUE MEASUREMENTS

The Company's assets and liabilities that are measured at fair value as of December 31, 2016, and December 31, 2015, are classified in the tables below in one of the three categories described in note 2r above:

	December 31, 2016		
	Level 1	Level 2	Total
Marketable securities	$957	$60,240	$61,197
Currency options designated as hedging instruments (current asset)	-	$2	$2

	December 31, 2015		
	Level 1	Level 2	Total
Marketable securities	$1,977	$54,770	$56,747
Currency options designated as hedging instruments (current liability)	-	$(5)	$(5)

The Company's corporate debt securities are traded in markets that are not considered to be active, but are valued based on quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Accordingly, these assets are categorized as Level 2.

The table below sets forth a summary of the changes in the fair value of the Company's financial liabilities classified as Level 3 (the derivative embedded in the convertible loans):

	2014	
	Warrants*	Embedded derivatives**
Balance at beginning of year	$-	$ 1,529
Warrants issued during the year	2,129	-
Changes in fair value during the year	6,365	680
Conversion of convertible loans	-	(2,209)
Conversion of warrants from preferred A warrants into ordinary share warrants	(8,494)	-

Balance at end of year	$-	$ -

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NOTE 3 - FAIR VALUE MEASURMENTS (continued):

* On September 17, 2014, as part of the Company's initial public offering all preferred A shares were converted into ordinary shares (see Note 9). As a result, all outstanding warrants to purchase Preferred A shares (see Note 9c) were transformed on that date ("the Conversion Date") in accordance with their original terms, to warrants to purchase ordinary shares. Based on relevant accounting principles, these warrants are considered equity instruments. Accordingly, on the Conversion Date, those warrants ceased to be accounted for as a liability and were recorded as equity.

The fair value of each of the warrants, on the Conversion Date, was determined by using the Black-Scholes model. The underlying data used for computing the fair value of the warrants were mainly as follows: $6 value of ordinary shares, 0% Dividend yield, 1.45% risk free interest rate, 65% expected volatility and 3.6 years expected term.

** As the convertible loans have been automatically converted on May 12, 2014, the change in fair value of the embedded derivative represents the difference between the carrying amount of the embedded as of December 31, 2013 and their original amount which have been recorded within the finance expenses. See note 8b.

Foreign exchange risk management

The Company purchases and writes options in order to hedge the currency exposure on the Company's cash flow. The currency hedged items are denominated in New Israeli Shekel (NIS). The purchasing and writing of options is part of a comprehensive currency hedging strategy. These transactions are at zero cost for periods of up to one year. The counterparty to the derivatives are major banks in Israel.

During February 2015, the Company began purchasing and writing options in respect of salary, rent and other expenses dominated in NIS for a period of up to a year ahead. These transactions qualify for cash flow hedge accounting. As of December 31, 2016 the Company recorded income in the amount of $13 in operating expenses relating to hedge transaction.

As of December 31, 2016 the total hedged amount was NIS 13.5 million.

As of December 31, 2016, the Company has a lien in the amount of $224 on the Company's marketable securities and a lien in the amount $250 on the Company's checking account, in respect of bank guarantees granted in order to secure the hedging transactions.

NOTE 4 - MARKETABLE SECURITIES

Marketable securities as of December 31, 2016, and December 31, 2015, consist mainly of debt and equity securities. These securities are classified as available-for-sale and are recorded at fair value. Changes in fair value, net of taxes (if applicable), are reflected in other comprehensive loss. Realized gains and losses on sales of the securities, as well as premium or discount amortization, are included in the consolidated statement of operations as finance income or expenses.

The following table sets forth the Company's marketable securities:

December 31

	2016	2015
Israeli mutual funds	$957	$1,977
Certificates of deposit	33,350	35,627
Municipal and agency bonds	26,890	19,143
Total	$61,197	$56,747

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 4 - MARKETABLE SECURITIES (continued):

At December 31, 2016 and 2015, the fair value, cost and gross unrealized holding gains of the securities owned by the Company were as follows:

	December 31, 2016			
	Fair value	Cost or Amortized cost	Gross unrealized holding loss	Gross unrealized holding gains
Israeli mutual funds	$957	$ 952	$ -	$ 5
Certificates of deposit	33,350	33,408	68	10
Agency bonds	26,890	26,901	13	2
Total	$61,197	$ 61,261	$ 81	$ 17

	December 31, 2015			
	Fair value	Cost or Amortized cost	Gross unrealized holding loss	Gross unrealized holding gains
Israeli mutual funds	$1,977	$ 1,978	$ 3	$ 2
Certificates of deposit	35,627	35,703	79	3
Municipal and agency bonds	19,143	19,191	49	1
Total	$56,747	$ 56,872	$ 131	$ 6

As of December 31, 2016, the unrealized losses attributed to the Company’s marketable securities were primarily due to credit spreads and interest rate movements. The Company has considered factors regarding other than temporary impaired securities and determined that there are no securities with impairment that is other than temporary as of December 31, 2016, and December 31, 2015.

During the year ended December 31, 2016 the Company received proceeds of $27,106 upon sale and maturity of marketable securities.

As of December 31, 2016, and December 31, 2015, the Company’s debt securities had the following maturity dates:

	Market value December 31	
	2016	2015
Due within one year	$42,708	$22,485
1 to 2 years	14,513	27,046
2 to 3 years	3,019	5,239
Total	$60,240	$54,770

$390 and $769 of the Company’s marketable securities were restricted as of December 31, 2016, and December 31, 2015, respectively, due to a lien in respect of bank guarantees granted to secure hedging transaction and the Company’s rent agreement. Refer to note 7 and note 3.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 5 - PROPERTY AND EQUIPMENT:

	December 31	
	2016	2015
Cost:		
Leasehold improvements	$229	$164
Computers and software	187	130
Laboratory equipment	896	768
Furniture	96	84
Vehicles*	198	175
	1,606	1,321
Less:		
Accumulated depreciation and amortization	668	675
Property and Equipment, net	$938	$646

* See note 8c relating to the lien on the Company’s vehicles.

Depreciation and amortization expense totaled $143, $87 and $33 for the years ended December 31, 2016, December 31 2015, and December 31, 2014, respectively.

During the years ended December 31, 2016 and December 31, 2015, the Company disposed of fixed assets in the net amount of $16 and $15 respectively.

NOTE 6 - EMPLOYEE SEVERANCE BENEFITS

The Company's liability for severance pay for its Israeli employees is calculated pursuant to Israeli severance pay law based on the most recent salary of the employee multiplied by the number of years of employment, as of the balance sheet date, less amounts funded in each employee’s severance fund. Such liability is recorded on the Company’s balance sheet under “Liability for employee severance benefits” as if it were payable at each balance sheet date on an undiscounted basis. The Company partially secures this liability by purchasing insurance policies or establishing dedicated severance accounts within the relevant employees’ pension funds, and making monthly deposits under such policies or into such accounts. The value of these policies is recorded as an asset in the Company's balance sheet.

During 2014, all of the Israeli employees agreed to the terms of Section 14 of the Israeli Severance Pay Law, 1963, according to which all deposits in the pension fund and/or with the insurance company, thereafter, exempt the Company from any additional obligation. These deposits are accounted as defined contribution payments and therefore not recorded on the Company’s balance sheet. Once the employees agreed to the terms of Section 14, all amounts funded on behalf of the employees were released to their full ownership. The liability for employee severance benefits as of December 31, 2016, represents the Company's obligation that has not been secured by deposits to employee severance funds.

The amount of severance payment expenses were $244, $193 and $157 for the years ended December 31, 2016, December 31, 2015 and December 31, 2014, respectively.

During 2017, the Company expects to deposit approximately $334 with respect to employee’s severance benefits.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 7 - COMMITMENTS

Lease agreement

The Company leases office space for its headquarters and research and development facilities in Israel and the United States of America under several lease agreements. The lease agreements for the facilities in Israel are linked to the Israeli CPI and expire between February 2017 and December 2020. The lease agreement in the United States is due to expire during August 2017.

Rental expenses for the years ended December 31, 2016, December 31, 2015 and December 31, 2014, were $358, $352 and $172, respectively.

Future minimum lease commitments under non-cancelable operating lease agreements are as follows:

2017	$498
2018	554
2019 and thereafter	1,112
Total	$2,164

The Company has a lien in the amount of $166 on the Company’s marketable securities in respect of bank guarantees granted in order to secure the lease agreements.

NOTE 8 - LOANS:

a. Loan from the BIRD foundation

During the second quarter of 2016, the Company repaid the loan received from the Israel United States Binational Industrial Research and Development Foundation (the "BIRD foundation") upon the completion of a certain clinical development. The loan, received in instalments between 2008 and 2011, was denominated in US dollars and linked to the US Consumer Price Index.

b. Convertible loans:

1) During the years 2011- 2013 the Company entered into two convertible loan agreements (“2011 loan agreement” and “2012 loan agreement”), with several of its existing shareholders and other lenders, to receive an aggregate amount of $5,096. The loans bore interest ranging between 6% and 8%.

2) During the first quarter of 2014, the Company reached an agreement with certain lenders of the 2011 convertible loans that were due to mature during that period, according to which the maturity date of those loans was deferred by one year and the interest rate was increased to 12% for the duration of the deferral period (the “amendment”).

The Company has concluded that the amendment to the terms of the 2011 convertible loans is not considered to be “substantially different” under ASC 470-50, as the difference between the present value of the original loan and the present value of the modified loan was approximately 3.7%. Accordingly, the amendment was accounted for prospectively as yield adjustment, based on the revised terms of the loans.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 8 - LOANS (continued):

3) Accounting treatment of the loans

2011 Convertible Loans: The automatic conversion feature in the loans has been bifurcated and accounted for as an embedded derivative, measured initially and subsequently at fair value with changes in fair value recorded as finance expenses. The bifurcated embedded derivative was presented in the Company's balance sheet on a combined basis with the related host contract. The loans were measured at amortized costs using the effective interest rate method.

2012 Convertible Loans: The automatic conversion feature in the loans was bifurcated and accounted for as an embedded derivative measured initially and subsequently at fair value with changes in fair value recorded as finance expenses. The bifurcated embedded derivative is presented in the Company's balance sheet on a combined basis with the related host contract.

The Company allocated the proceeds from its issuance of a unit consisting of 2012 convertible loans along with ordinary shares between the convertible loans and the ordinary shares based on their relative fair values at the issuance date of the unit. Then, the Company recorded the embedded derivative feature based on its fair value at the issuance date, and the remaining amount (i.e., the proceeds allocated to the convertible loans less the fair value of the embedded derivative feature) was attributed to the convertible loans.

In accordance with ASC 470-20, “Debt with Conversion and Other Options,” the Company determined that a BCF existed at the issuance date of the 2012 convertible loans. The BCF was recorded in equity and the loans net of the amount of BCF assigned to them are measured at amortized costs using the effective interest rate method.

Accordingly, the Company allocated the proceeds from the 2012 loans between these components as follows:

(i) of the $1,448 of 2012 loans received in 2012, $111 were attributed to the embedded derivative, $839 were attributed to the convertible loans and $498 were attributed to the shares. In addition, an amount of $668 was recognized as a BCF against the 2012 convertible loans, resulting in a presentation of these loans (including the embedded derivative) at a net value of $282 at issuance date. The Company used Level 3 assumptions in arriving at fair value in order to appropriately allocate the proceeds: fair value of the issued shares was $1,214 and fair value of the convertible loans $2,319.

(ii) of the to $1,500 of 2012 loans received in 2013, $215 were attributed to the embedded derivative, $689 were attributed to the loans and $596 were attributed to the shares. In addition, an amount of $689 was recognized as a BCF against the 2012 convertible loans, resulting in a presentation of these loans (including the embedded derivative) at a net value of $ 215 at issuance date. The Company used Level 3 assumptions in arriving at fair value in order to appropriately allocate the proceeds: fair value of the issued shares was $1,752 and fair value of the convertible loans $2,662.

4) The 2014 financing round (see Note 9b) was a qualified round for purposes of the 2011 and 2012 convertible loan agreements. Accordingly, all principal and accrued interest outstanding under such loan agreements were converted into a total of 1,010,350 Preferred A Shares and 505,175 warrants to purchase preferred A shares. Refer to note 9d regarding the conversion of the Preferred A Shares and warrants into Ordinary Shares and warrants.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 8 - LOANS (continued):

In accordance with the amended convertible loan agreements, the lenders were entitled to receive, upon conversion, a total of 1,010,350 warrants to purchase preferred A shares (hereinafter “the warrants”). However, the lenders, who were also shareholders of the Company, agreed to receive only half of the warrants that they were entitled to receive in accordance with the loan agreements. The value of the waiver of 505,175 warrants, amounting to $686, was recorded as a capital contribution.

Upon the automatic conversion of the convertible loans, the difference at conversion date between their carrying amount (taking into account the balance of the remaining beneficial conversion feature (BCF) the discount from the allocation of proceeds to the Ordinary Shares and the embedded derivatives) and their fixed monetary amount used for conversion in the amount of $3,520, has been recorded in the statements of operations as finance expenses.

c. Bank Borrowings

During 2014 the Company entered into several finance agreements with a bank in order to finance the purchase of vehicles (hereinafter “the loans”). The loans are denominated in NIS and bear interest at a rate per annum equal to Prime minus 0.5%. The loans are repayable in 36 monthly payments. The total amounts received as part of the agreement were $102.

In order to secure the loans the bank recorded a lien on the Company’s vehicles.

NOTE 9 - SHARE CAPITAL:

a. Rights of the Company’s ordinary shares

Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

b. Financing round

During the second quarter of 2014, the Company completed a private placement (the "2014 financing round") with a group of new investors and several of its existing shareholders, raising a total of $8,157, net of $123 issuance costs, in consideration of 1,036,431 Preferred A Shares par value 0.16 NIS and 1,061,469 warrants to purchase Preferred A Shares (see also d. below). The 2014 financing round closed in two phases, the first on May 13, 2014, and the second on June 3, 2014 (respectively – "closing date"), raising a gross amount of $6,580 and $1,700, respectively.

c. Public offerings

In September 2014, the Company completed an IPO, pursuant to which the Company issued 7,668,200 ordinary shares (including underwriters ‘green shoe’), NIS 0.16 par value (“Ordinary Shares”) at $6.00 per share raising a total of approximately $41,100, net of underwriting discounts, commissions and other offering expenses. Upon the completion of the Company’s IPO, all outstanding series A preferred shares were automatically converted into Ordinary Shares.

On April 20, 2015, the Company completed a follow-on public offering. A total of 7,419,353 ordinary shares were sold at a price of $9.30 per share. Prior to closing, the underwriters fully exercised their option to purchase 967,741

additional ordinary shares. The net proceeds from the sale of shares, after deducting underwriting discounts, commissions and other offering expenses, were approximately $64,202.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 9 - SHARE CAPITAL (continued):

On September 30, 2016, the Company completed an additional offering in which 5,700,000 ordinary shares were sold at a price of $9.50 per share. On October 28, 2016, the underwriters partially exercised their ‘green shoe’ option and purchased 411,959 additional ordinary shares. The net proceeds, including the underwriters' option, were approximately $54,132, after deducting underwriter’s discounts, commissions and other offering expenses.

d. Preferred A shares and warrants conversion

In accordance with the Company’s Articles of association (the “Articles“) the initial conversion ratio of each Preferred A Share was set out to be 1:1. As the conversion rate of the Preferred A Shares was greater than 70% of the price per share of the shares issued at the closing of the IPO, the price protection provisions, as defined in the Articles, was triggered and caused the following: (a) the automatic reduction of the conversion price of the Preferred A Shares to a conversion price of 70% of the price paid for the newly issued shares; (b) the increase of the outstanding warrants granted to the 2014 financing round investors and lenders to a total of 2,716,956 warrants and the reduction of the warrants’ exercise price to 70% of the price paid for the newly issued shares which amounted to an exercise price of $5.04 per warrant.

Per the above, upon the completion of the IPO, the total amount of 2,046,781 Preferred A Shares were converted into 3,367,244 Ordinary Shares.

e. Warrants

Pursuant to the IPO, the warrants to purchase Preferred A Shares were automatically converted into warrants to purchase Ordinary Shares. Each warrant can be exercised for one ordinary share at an exercise price of $5.04 per share or through a cashless exercise. The warrants are exercisable until the fourth anniversary of the closing date of the 2014 financing round (May or June 2018).

During the year ended December 31, 2016, 257,137 warrants were exercised into 257,137 ordinary shares. During the year ended December 31, 2015, 652,019 warrants were exercised into 546,322 ordinary shares. As of December 31, 2016, and December 31, 2015, the total amount of warrants outstanding were 1,807,800 and 2,064,937, respectively.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 9 - SHARE CAPITAL (continued):

f. Share-based compensation

In June 2009, the Company’s Board of Directors approved a share option plan and reserved a pool of 1,635,694 ordinary shares for grant to Company employees, consultants, directors and other service providers.

In May 2015, the Company's board of directors approved a new option plan (the "Plan") replacing the previous plan approved in 2009. The Plan includes a pool of 2,690,694 ordinary shares for grant to Company employees, consultants, directors and other service providers.

As of December 31, 2016, 845,858 shares remain available for grant under the Plan. As for the increase of the pool, refer to note 13, Subsequent events.

The Plan is designed to enable the Company to grant options to purchase Ordinary Shares and RSUs under various and different tax regimes including, without limitation: (i) pursuant and subject to Section 102 of the Tax Ordinance or any provision which may amend or replace it and any regulations, rules, orders or procedures promulgated thereunder and to designate them as either grants made through a trustee or not through a trustee; and (ii) pursuant and subject to Section 3(i) of the Tax Ordinance.

The fair value of each option granted is estimated using the Black-Scholes option pricing method. The volatility is based on a combination of the Company’s historical volatility, historical volatilities of companies in comparable stages as well as companies in the industry, by statistical analysis of daily share pricing model. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The Company’s management uses the contractual term or its expectations, as applicable, of each option as its expected life. The expected term of the options granted is derived from the output of the option pricing model and represents the period of time that granted options are expected to remain outstanding.

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NOTE 9 - SHARE CAPITAL (continued):

In the years ended December 31, 2016, December 31, 2015 and December 31, 2014, the Company granted options to employees and non-employees as follows:

	Year ended December 31 2016			
	Award amount	Exercise price range	Vesting period	Expiration
Employees:				
Options	715,310	$6.04- $8.54	4 years	10 years
RSU	25,000	-	4 years	10 years
Directors:				
Options	24,000	$7.09	3 years	10 years
Consultants:				
Options	4,800	$6.34	4 years	10 years

	Year ended December 31 2015			
	Award amount	Exercise price range	Vesting period	Expiration
Employees:				
Options	852,501	$6.77- $10.88	4 years	10 years
RSU	216,050	-	4 years	10 years
Directors:				
Options	27,000	$10.80-$11.87	3 years	10 years
Consultants:				
Options	4,000	$10.88	4 years	10 years
RSU	83,800	-	4 years	10 years

	Year ended December 31 2014			
	Award amount	Exercise price range	Vesting period	Expiration
Employees:				
Options	217,000	$1.92- $7.98	4 years	10 years
Directors:				
Options	231,000	$5.88	3 years	10 years
Consultants:				
Options	46,875	$1.92- $7.98	0-6 years	6 years

The fair value of options and RSUs granted to employees and directors during 2016, 2015 and 2014 was $2,816, $6,592 and $1,683 respectively. The fair value of options and RSUs granted to consultants during the years ended

2016, 2015 and 2014 was $42, $686 and $183 respectively.

The fair value of RSUs granted to employees is based on the share price on grant date.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 9 - SHARE CAPITAL (continued):

The fair value of options granted to employees and directors on the date of grant was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31		
	2016	2015	2014
Value of ordinary share	$5.9-$8.35	$6.96-$11.3	$4.8-$6.8
Dividend yield	0 %	0 %	0 %
Expected volatility	60.3%-63.2%	60.1%-64.9 %	59.0%-66.7%
Risk-free interest rate	1.25%-1.86%	1.38%-1.98 %	1.87%-2.22%
Expected term	6 years	6 years	6-7 years

The total unrecognized compensation cost of employee options and RSUs at December 31, 2016 is $6,743 which is expected to be recognized over a weighted average period of 2 years.

The fair value of RSUs granted to consultants is based on the share price on December 31, 2016.

The fair value of options granted during 2016, 2015 and 2014 to consultants, was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	December 31		
	2016	2015	2014
Value of ordinary share	$11.1	$8.11	$5.45-$7.01
Dividend yield	0 %	0 %	0 %
Expected volatility	64.8 %	69.4 %	59.9%-62.0 %
Risk-free interest rate	2.38 %	2.27 %	1.81%-2.0 %
Expected term	9 years	10 years	6 years

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NOTE 9 - SHARE CAPITAL (continued):

The following table summarizes the number of options outstanding for the years ended December 31, 2016, December 31, 2015 and December 31, 2014, and related information:

	Employees and directors		Consultants and service providers	
	Number of options	USD[1]	Number of options	USD[1]
Outstanding at January 1, 2014	462,500	$ 1.28	220,000	$ 1.28
Granted	448,000	5.32	46,875	5.96
Forfeited	(6,250)	1.92	-	-
Outstanding at December 31, 2014	904,250	3.28	266,875	2.10
Granted	879,501	7.72	4,000	10.88
Exercised	(29,525)	1.92	(150,000)	1.92
Re-Designated[2]	(27,000)	5.88	27,000	5.88
Outstanding at December 31, 2015	1,727,226	5.41	147,875	3.24
Granted	739,310	6.55	4,800	6.34
Forfeited	(20,000)	6.66	(15,625)	7.98
Exercised	(69,444)	1.64	-	-
Outstanding at December 31, 2016	2,377,092	$ 5.87	137,050	$ 2.81

(1) Weighted average price per share

(2) Pursuant to change in status of grantee from ‘director’ to ‘consultant’ during the reporting period.

The following table summarizes the number of RSUs outstanding for the years ended December 31, 2016 and December 31, 2015:

	Employees and directors	Consultants and service providers
	Number of RSUs	
Outstanding at January 1, 2015	-	-
Awarded	216,050	83,800
Vested	(29,250)	(20,750)
Outstanding at December 31, 2015	186,800	63,050
Awarded	25,000	-
Vested	(69,117)	(21,000)
Outstanding at December 31, 2016	142,683	42,050

The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2016:

	December 31, 2016			
	Options outstanding		Options exercisable	
	Number of	Weighted	Number of	Weighted

Exercise prices per share (USD)	options outstanding at end of year	average remaining contractual life	options exercisable at end of year	Average Remaining contractual Life
0.048-1.312	283,125	2.90	283,125	2.90
1.92	291,031	5.19	258,219	4.93
5.46-5.88	279,250	7.98	182,950	7.98
6.04-6.77	753,110	8.95	72,000	8.02
7.093-8.544	757,126	8.82	171,563	8.46
10.8-11.87	150,500	8.60	47,594	8.60
	2,514,142		1,015,450	

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 9 - SHARE CAPITAL (continued):

The aggregate intrinsic value of the total outstanding and exercisable options as of December 31, 2016, is $13,598 and $7,310 respectively.

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31		
	2016	2015	2014
Cost of revenues	$ 3	$ 2	$ 15
Research and development expenses	1,135	588	80
Selling, general and administrative	1,774	1,187	102
	$ 2,912	$ 1,777	$ 197

NOTE 10 - INCOME TAX:

The Company is taxed under Israel and the United States of America tax laws:

a. Tax rates:

1) Income from Israel was taxed at the corporate tax rate of 26.5% in 2014, 26.5% in 2015, and 25% in 2016. Capital gains are subject to capital gain tax, which equals to 25%.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate in 2016 and thereafter, from 26.5% to 25%.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate will be 24% in 2017 and 23% in 2018 and thereafter.

2) Income of the subsidiary is taxed according to the federal tax laws in the US and the relevant state laws. The relevant federal tax rates for 2016, 2015 and 2014 were 35%, 30% and 15%, respectively. The relevant state tax rate for 2016 and 2015 was 9% whereas the state tax rate for 2014 was 7.5%.

b. Tax assessments

Foamix has tax assessments that are considered to be final through tax year 2012.

c. Tax benefits under the Law for Encouragement of Industry (Taxation), 1969

The Company believes that it currently qualifies as an "Industrial Company" under the above law. As such it is entitled to certain tax benefits, mainly the right to deduct share issuance costs over three years for tax purposes in the event of a public offering.

The Company utilizes this tax benefit.

d. Losses for tax purposes carried forward to future years

As of December 31, 2016, Foamix had approximately $50.1 million of net carry forward tax losses in Israel, which are available to reduce future taxable income with no limited period of use.

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
(U.S. dollars in thousands, except share and per share amounts)

NOTE 10 - INCOME TAX (continued):

e. Subsidiary tax liability

During 2016, 2015 and 2014, the US subsidiary incurred a tax expense in the amount of $387, $39 and $6, respectively.

f. Deferred income taxes:

	December 31,	
	2016	2015
In respect of:		
Net operating loss carry forward	$11,512	$ 8,142
Research and development	4,147	1,773
Other	332	299
Less - valuation allowance	(15,991)	(10,214)
Net deferred tax assets	$-	$ -

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forward losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not likely, the Company recorded a full valuation allowance.

Deferred tax has not been provided on taxes that would apply in the event of disposal of the investments in the subsidiary, as it is the Company's intention to hold this investment and not to realize it.

Foamix may incur an additional tax liability in the event of an inter-company dividend distribution from its subsidiary; no additional deferred taxes have been provided, since it is the Company's policy not to distribute in the foreseeable future, dividends which would result in additional tax liability.

Following is a reconciliation of the theoretical tax benefit, assuming all income is taxed at the statutory corporate tax rate applicable to Israeli corporations, and the actual tax expense:

	Year ended December 31		
	2016	2015	2014
Loss before income taxes	$28,949	$16,478	$11,478
Theoretical tax benefit on the above amount	(7,237)	(4,367)	(3,042)
Decrease (increase) in tax refund resulting from:			
Reduction in corporate tax rate	1,965	-	-
Non-deductible expenses and other permanent differences, mainly share based compensation expenses, issuance costs and finance expenses on convertible loans and warrants	(491)	(585)	2,706
Net change in valuation allowance	5,777	3,973	1,757
Other	373	1,018	(1,415)
Actual tax expense	$387	$39	$6

g. As of December 31, 2016, and December 31, 2015, the Company had not accrued a provision for uncertain tax positions.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 10 - INCOME TAX (continued):

h. Roll forward of valuation allowance:

Balance at January 1, 2014	$4,484
Additions	1,757
Balance at December 31, 2014	$6,241
Additions	3,973
Balance at December 31, 2015	$10,214
Additions	5,777
Balance at December 31, 2016	$15,991

NOTE 11 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31	
	2016	2015
a. Account receivable - other:		
Institutions	$174	$122
Prepaid expenses	246	346
Other	18	3
	$438	$471
b. Accounts payable and accruals - other:		
Accrued expenses	$709	$558
Payroll and related institutions	581	451
Bonus accrual	1,661	1,140
Other	33	20
	$2,984	$2,169

Statements of operations:

c. Revenues

In the year ended December 31, 2016, the Company's revenues were driven virtually all from one main customer. Based on the agreement with this customer the Company is entitled to royalty payments with respect to sales of a product developed by the customer in collaboration with the Company. Additionally, the Company was entitled to contingent payments for the achievement of certain sale targets by the customer.

The following table provides a breakdown of the Company's net revenues:

	Year ended December 31		
	2016	2015	2014
Development Service Payments	$63	$596	$4,814
Contingent Payments	2,500	-	600

Royalties	2,964	253	-
Total revenues	$ 5,527	$ 849	$ 5,414

FOAMIX PHARMACEUTICALS LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)
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NOTE 11 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):

d. Finance expenses (income), net:

Finance expenses:			
Finance expenses on convertible loans and warrants	$-	$-	$9,915
Finance expenses on BIRD loan	243	*	*
Other expenses	17	23	15
Total finance expenses	260	23	9,930
Finance income:			
Gains from securities, net	(401)	(180)	(11)
Interest on bank deposits	(536)	(289)	(28)
Foreign exchange gains, net	(24)	(6)	(47)
Total finance income	(961)	(475)	(86)
	$(701)	$(452)	$9,844

* Represents an amount less than $1.

NOTE 12 - ENTITY-WIDE DISCLOSURE:

a. Net revenues by geographic area were as follows:

	Year ended December 31		
	2016	2015	2014
Germany	$5,464	$253	$2,500
United States	14	587	2,305
France	49	9	-
Israel	-	-	609
Total revenues	$5,527	$849	$5,414

b. Revenues from principal customers - revenues from single customers that exceed 10% of total revenues in the relevant year:

	Year ended December 31		
	2016	2015	2014
Customer A	$-	$86	$732
Customer B	$14	$366	$1,032
Customer C	$5,464	$253	$2,500
Customer D	$-	$135	$541
Customer E	$-	$-	$609

NOTE 13 - SUBSEQUENT EVENTS

In November, 2016, the board of directors approved an increase of 900,000 ordinary shares, to the pool included under the option Plan. The shares were registered in January 2017.