UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019
or

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

For the transition period from to

Commission File Number 001-36621

Foamix Pharmaceuticals Ltd.

(Exact name of registrant as specified in its charter)

Israel	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2 Holzman Street, Weizmann Science Park
Rehovot 7670402, Israel
(Address of principal executive offices, including zip code)

+972-8-9316233
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on Which Registered:
Ordinary shares, par value NIS 0.16 per share	**FOMX**	**The Nasdaq Stock Market LLC**

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

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

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes ☐ No ☒

The aggregate market value of the registrant's ordinary shares, par value NIS 0.16 per share, held by non-affiliates of the registrant on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $129.2 million (based on the closing sales price of the registrant's ordinary shares on that date). Ordinary shares held by each director and executive officer of the registrant, as well as shares held by each holder of more than 10% of the ordinary shares known to the registrant, have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The total number of shares outstanding of the registrant's ordinary shares, par value NIS 0.16 per share, as of March 1, 2020, was 61,634,707.

Foamix Pharmaceuticals Ltd. meets the conditions set forth in General Instruction I(1)(a) and (b) of Form 10-K and is therefore filing this Form with the reduced disclosure format.

DOCUMENTS INCORPORATED BY REFERENCE

None

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EXPLANATORY NOTE

On November 10, 2019, Foamix Pharmaceuticals Ltd. ("Foamix") entered into an Agreement and Plan of Merger (as amended by Amendment No. 1 to the Agreement and Plan of Merger, dated as of December 4, 2019, the "Merger Agreement") with Menlo Therapeutics Inc. ("Menlo"), a Delaware corporation, and Giants Merger Subsidiary Ltd. ("Merger Sub"), a direct and wholly-owned Israeli subsidiary of Menlo, whereby Merger Sub agreed to merge with and into Foamix, with Foamix continuing as the surviving corporation and a wholly-owned subsidiary of Menlo (the "Merger"). On March 9, 2020, the Merger was completed, and, as of the date of this Annual Report on Form 10-K (this "Annual Report"), Foamix is a wholly-owned subsidiary of Menlo.

This Annual Report only includes information with respect to Foamix and does not include a description of the business of Foamix and Menlo as a combined company, nor does it include any financial information about the combined company. We urge Foamix shareholders to review Menlo's filings made with the SEC, including Menlo's most recent Annual Report on Form 10-K filed on March 3, 2020 for a description of Menlo's business and risks associated therewith. In particular, Foamix shareholders should review Menlo's risk factors that discuss their ongoing clinical trials with respect to serlopitant.

DEFINITIONS

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 the "Board" or the "board of directors" are to the Company's board of directors;

References to the "Companies Law" are to Israel's Companies Law, 5759-1999, as currently amended;

References to the "Efficacy Determination" means (i) the top-line primary endpoint results of both Phase III PN Trials as delivered in the form set forth (and subject to the terms and conditions set forth) in Exhibit 2.4(g)(ii) of the Merger Agreement by QST Consultations, LTD to Menlo and Foamix; or (ii) if the top-line primary endpoint results of only one Phase III PN Trial is delivered in the form set forth (and subject to the terms and conditions set forth) in Exhibit 2.4(g)(ii) of the Merger Agreement by QST Consultations, LTD to Menlo and Foamix on or before May 31, 2020, such results as delivered in such form.

References to the "Exchange Act" are to the Securities Exchange Act of 1934, as amended;

References to the "FDA" are to the United States Food and Drug Administration;

References to "Menlo" are to Menlo Therapeutics Inc.;

References to the "Merger Agreement" mean the Agreement and Plan of Merger, dated as of November 10, 2019, by and among Foamix, Menlo and Merger Sub, as amended by Amendment No. 1 to the Agreement and Plan of Merger, dated as of December 4, 2019;

References to "Nasdaq" are to the Nasdaq Global Stock Market;

References to "ordinary shares" are to our ordinary shares, par value of NIS 0.16 per share;

References to "Phase III PN Trials" mean the Phase III double-blinded, placebo-controlled trials for the treatment of pruritus associated with prurigo nodularis, referenced by Protocol Numbers MTI-105 (United States) and MTI-106 (Europe), and being conducted by Synteract, Inc. and TFS International AB, respectively;

References to the "SEC" are to the United States Securities and Exchange Commission;

References to the "Securities Act" are to the Securities Act of 1933, as amended; and

References to "U.S. dollars" and "$" are to currency of the United States of America, and references to "NIS" are to New Israeli Shekels.

USE OF TRADEMARKS

"Foamix," the Foamix logo and other trademarks or service marks of Foamix, or AMZEEQ and MST that identify our recently FDA-approved topical product for acne vulgaris and its delivery technology, appearing in this Annual Report on Form 10-K, are the property of Foamix. This Annual Report also contains trade names, trademarks and service marks of others, which

are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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:

- FDA approval of, or other regulatory action in the United States and elsewhere with respect to, our product candidates;
- the commercialization of AMZEEQ and current or future product candidates;
- our ability to achieve favorable pricing for AMZEEQ and product candidates;
- our expectations regarding the commercial supply of AMZEEQ and product candidates;
- third-party payor reimbursement for AMZEEQ and product candidates;
- our estimates regarding anticipated expenses, capital requirements and needs for additional financing;
- the potential market size of treatments for any diseases and market adoption of our products by physicians and patients;
- the timing, cost or other aspects of the commercialization of AMZEEQ and product candidates;
- the completion of, 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 USPTO, and other governmental patent agencies;
- the timing, costs or results of litigation to protect our intellectual property portfolio;
- development and approval of the use of our product candidates for additional indications;
- our expectations regarding licensing, business transactions and strategic operations; and
- the ability to successfully integrate our business with Menlo.

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 Annual Report 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 "Risk Factors" and in our other filings with 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.

STATEMENTS BY RESEARCH OR FORECAST FIRMS

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.

PART I

ITEM 1 - BUSINESS

Overview of Foamix's Business

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies in dermatology. Utilizing our expertise in the development of topical minocycline, we are working to develop and commercialize topical drugs for dermatological therapy, including the first topical minocycline products in the United States. On October 18, 2019, the FDA approved our first drug product, AMZEEQ™ (minocycline) topical foam, 4%, formerly known as FMX101 ("AMZEEQ"), a once-daily topical antibiotic for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older. AMZEEQ is the first topical minocycline to be approved by the FDA for any condition. AMZEEQ became available for prescribing on January 13, 2020.

Consummation of the Merger with Menlo Therapeutics Inc.

On November 10, 2019, we entered into the Merger Agreement with Menlo and Merger Sub whereby Merger Sub agreed to merge with and into Foamix, with Foamix continuing as the surviving corporation and a wholly-owned subsidiary of Menlo. Menlo, which completed its initial public offering in January 2018 and is listed on the Nasdaq Global Select Market under the symbol "MNLO", is a late-stage biopharmaceutical company focused on the development and commercialization of serlopitant, an NK1 receptor antagonist given as a once-daily oral tablet for the treatment of pruritus, or itch, associated with various conditions such as prurigo nodularis ("PN") and psoriasis. Menlo's clinical development program for serlopitant includes two ongoing Phase III clinical trials for the treatment of pruritus associated with PN and a Phase III-ready clinical program for the treatment of pruritus associated with psoriasis. On March 9, 2020 (the "Effective Date"), the Merger was completed and Foamix is now a wholly-owned subsidiary of Menlo. Foamix will cease to be a reporting company as of March 19, 2020 and all future filings of the combined company will be made by Menlo.

On the Effective Date, each ordinary share of Foamix was exchanged for 0.5924 shares of common stock of Menlo (the "Exchange Ratio"). In addition, on the Effective Date, Foamix shareholders received one contingent stock right (a "CSR") for each Foamix ordinary share held by them. The CSRs are governed by the Contingent Stock Rights Agreement (the "CSR Agreement"), dated as of March 9, 2020, by and between Menlo and American Stock Transfer & Trust Company, LLC, and represent the non-transferable contractual right to receive shares of common stock of Menlo if specified events occur within agreed time periods. Pursuant to the CSR Agreement, each CSR may become convertible upon the occurrence of the events described below, and, if so converted, will entitle its holder to receive from Menlo additional shares of Menlo common stock. The CSR events relate to Menlo's Phase III PN Trials. The CSRs may become convertible and additional shares of Menlo common stock may become payable to the rights agent, for subsequent distribution to the holders of the CSRs, upon the occurrence of the following events:

- if, on or prior to May 31, 2020, the Efficacy Determination reports that proof of statistically significant superiority of serlopitant treatment over placebo treatment on the primary endpoint, as set out in the Merger Agreement ("Serlopitant Significance"), was achieved in one Phase III PN Trial but was not achieved (or has not been determined) in the other Phase III PN Trial, each CSR will be converted into 0.6815 shares of Menlo common stock pursuant to the terms and conditions of the CSR Agreement. Following such Efficacy Determination, the effective Exchange Ratio in the Merger will be 1.2739 shares of Menlo common stock for each Foamix ordinary share, increasing the former Foamix shareholders' ownership of the outstanding share capital of the combined company to approximately 76% and correspondingly decreasing the pre-Merger Menlo stockholders' ownership of the outstanding share capital of the combined company to approximately 24%, each calculated on a fully diluted basis (with such percentages calculated as if the CSR conversion to additional shares occurred on the Effective Date); and

- if, on or prior to May 31, 2020, the Efficacy Determination reports that Serlopitant Significance was not achieved in either of the Phase III PN Trials, or if the Efficacy Determination has not been delivered on or before May 31, 2020, each CSR will be converted into 1.2082 shares of Menlo common stock pursuant to the terms and conditions of the CSR Agreement. Following such Efficacy Determination, the effective Exchange Ratio in the Merger will be 1.8006 shares of Menlo common stock for each Foamix ordinary share, increasing the former Foamix shareholders' ownership of the outstanding share capital of the combined company to approximately 82% and correspondingly decreasing the pre-Merger Menlo stockholders' ownership of the outstanding share capital of the combined company to approximately 18%, each calculated on a fully diluted basis (with such percentages calculated as if the CSR conversion to additional shares occurred on the Effective Date).

If the Efficacy Determination reports that Serlopitant Significance was demonstrated in both Phase III PN Trials, the CSRs will automatically be terminated, and their holders will not be entitled to any additional shares of Menlo common stock pursuant to the CSR or the CSR Agreement. The effective Exchange Ratio in the Merger will remain 0.5924 shares of Menlo common stock for each Foamix ordinary share and former Foamix shareholders will maintain their ownership of approximately 59% of the outstanding share capital of the combined company, with the Menlo stockholders owning the remaining 41% of the outstanding share capital of the combined company, each calculated on a fully diluted basis.

This Annual Report only includes information with respect to Foamix and does not include a description of the business of Foamix and Menlo as a combined company, nor does it include any financial information about the combined company. We urge Foamix shareholders to review Menlo's filings made with the SEC, including Menlo's most recent Annual Report on Form 10-K filed on March 3, 2020 for a description of Menlo's business and risks associated therewith. In particular, Foamix shareholders should review Menlo's risk factors that discuss their ongoing clinical trials with respect to serlopitant.

Foamix Product Pipeline

In October 2019, we announced that the FDA accepted our New Drug Application, or NDA, and set a target Prescription Drug User Fee ACT, or PDUFA, action date of June 2, 2020 for our late-stage drug product candidate, FMX103 (1.5% minocycline foam), for the treatment of moderate-to-severe papulopustular rosacea in adults. In November 2018, we announced that both of our Phase III clinical trials for FMX103 (Studies FX2016-11 and FX2016-12) met each of their co-primary endpoints, demonstrating a statistically significant reduction in inflammatory lesion counts and IGA treatment success, as assessed by Investigator's Global Assessment, or IGA, scores of approximately 50% from baseline. There were very few reported adverse events and no treatment-related serious adverse events observed in these Phase III clinical trials, as well as in the 40-week open label safety extension (Study FX2016-13) that was completed in February 2019. We cannot provide any assurances or predict with any certainty the schedule for which we will receive approval for FMX103, if at all.

Both AMZEEQ and FMX103 were developed using our Molecule Stabilizing Technology (MST™) vehicle, a proprietary foam platform designed to optimize the topical delivery of minocycline, an active pharmaceutical ingredient, or API, that was commercially available only in oral form until the FDA's approval of AMZEEQ.

In addition, we have proprietary delivery technologies in development that enable topical delivery of other APIs, each having unique pharmacological features and characteristics designed to keep the API stable when delivered and directed to the target site. We believe our MST vehicle and other topical delivery platforms may offer significant advantages over alternative delivery options and can be generally applicable for multiple application sites across a range of conditions.

We are currently developing a pipeline of other innovative product candidates to enhance our minocycline platform, including FCD105, a topical combination foam for the treatment of moderate-to-severe acne vulgaris, comprising minocycline 3% and adapalene 0.3%. In September 2019, we announced that the first patient was enrolled in our Phase II clinical trial (Study FX2016-40) to evaluate the efficacy and safety of FCD105. In November 2019, we announced that enrollment had been completed for this clinical trial, and we expect topline data from this Phase II clinical trial in the second quarter of 2020. Pending a successful development program, we intend to file an NDA for FCD105 under the FDA 505(b)(2) regulatory pathway, which is the same regulatory pathway we have pursued for AMZEEQ and are pursuing for FMX103.

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 LEO Pharma A/S, or LEO, Mylan N.V. and Actavis plc, combining our emulsion-based foam technology with drugs selected by the licensee to create new product offerings for patients. This licensed technology is different from the technology used in AMZEEQ and in our pipeline products. 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.

In September 2015, Bayer HealthCare AG, or Bayer, began selling in the United States a product branded Finacea, based on our foam technology. Finacea is a prescription topical drug which was developed through a 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 United States. Bayer listed in the Orange Book several patents that were licensed from us in connection with the development of Finacea. According to our initial license agreement with Bayer, we are entitled to receive royalties and certain contingent payments upon the commercialization of Finacea. On September 4, 2018, LEO acquired Finacea from Bayer. As part of the acquisition, our license agreement with Bayer with respect to Finacea was assigned to LEO. LEO has assumed all of the rights and responsibilities of Bayer under the license agreement as it relates to Finacea, including the payment of royalties to us and rights and obligations related to patent litigation matters.

In April 2019, our partner, LEO, informed us that the batches of API intended for use in Finacea and produced by a contract manufacturer had failed to meet the required specifications for the finished product and has been unable to manufacture the Finacea product for sale, which, in turn, reduced the royalty payments from LEO to us since that time. LEO has informed us that they are working diligently to address the issue in order to be able to produce sufficient supply of the finished product to meet the demand for Finacea in the market. We do not know when the production of Finacea will resume, if at all. This supply chain issue for Finacea is unrelated to our manufacturing, production or supply of AMZEEQ, FMX103 or any of our other product candidates. In 2019, we received (or became entitled to receive) a total of $0.4 million in royalties from sales of Finacea from LEO.

Together with LEO, we are litigating against Taro Pharmaceuticals Industries Ltd., or Taro, for its alleged infringement of certain of our patents following Taro's submission of an ANDA to the FDA seeking approval to manufacture and sell a generic version of Finacea. See also "Risk Factors—Risks Related to Our Intellectual Property—We have received notice letters of ANDAs submitted for drug products that are generic versions of Finacea foam and we are involved in lawsuits to protect and enforce our patents, which are expensive, time consuming and may be unsuccessful." In 2019, we, together with LEO, separately settled similar patent litigation with affiliates of Perrigo Company plc and Teva Pharmaceuticals Industries Ltd.

Intellectual Property

Our intellectual property and proprietary technology are essential to the development, manufacture, and sale of AMZEEQ and FMX103 and our future pipeline product candidates. We are committed to protecting our intellectual property rights, 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.

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 face and may face competition from many different sources with respect to AMZEEQ, which is available for purchase, our Phase III product candidate 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.

Currently marketed products that may compete with AMZEEQ include: (a) oral products such as Solodyn (minocycline, Bausch Health), Doryx (doxycycline, Mayne Pharmaceuticals), Targadox (doxycycline, Journey), Acticlate (docycycline, Almirall), Seysara (sarecycline, Almirall) and (b) topical products such as Epiduo (adapalene + benzoyl peroxide ("BPO"), Galderma), Aczone (dapsone, Almirall), Retin-A (tretinoin, Bausch Health), Onexton-Acanya (clindamycin + BPO, Bausch Health) and Tazorac (tazarotene, Almirall).

Currently marketed products that may compete with our FMX103 product candidate include: (a) branded and generic oral products containing minocycline (off-label), Oracea (doxycycline, Galderma) and (b) topical products such as all forms of metrogel/metronidazole available as a branded or generic product, Soolantra (ivermectin, Galderma) and Finacea (azaleic acid, LEO).

In addition, new products are currently being developed that may compete with AMZEEQ and our FMX103 product candidate, if approved, including: generic versions of any of the above on-marketed products and, specifically for acne: Twyneo (tretinoin + BPO, Sol-Gel) and Clascoterone (Cassiopea) and specifically for papulopustular rosacea: Epsolay (BPO, Sol-Gel). In September 2019 – Hovione Farmaciencia SA announced details of its planned Minocycline Against Rosacea Study, Phase III development program for the treatment of moderate to severe inflammatory rosacea with HY01 a 3% topical gel suspension containing minocycline non-hydrochloride. In January 2020, BioPharmX Corporation entered into a Merger Agreement with Timber Pharmaceuticals LLC. and says that following the merger the combined company will "evaluate BioPharmX's Phase III ready proprietary topical minocycline gel programs" This product has previously been studied by BioPharmX in the treatment of inflammatory lesions of acne vulgaris and papulopustular rosacea. In 2019, Sol-Gel completed Phase III studies for EPSOLAY® (microencapsulated benzoyl peroxide cream, 5%) for i*nflammatory lesions of Rosacea*, and for TWYNEO® (microencapsulated benzoyl peroxide, 3% and microencapsulated tretinoin, 0.1%) for *Acne Vulgaris.* If ultimately approved and launched in the United States, these products candidates could be direct competitors to AMZEEQ and FMX103.

Corporate Information

Following the consummation of the Merger on the Effective Date, Foamix became a wholly-owned subsidiary of Menlo. The combined company is incorporated in Delaware. In addition, Menlo will continue as an "emerging growth company," as defined in Section 2(a) of the Securities Act and as modified by the JOBS Act and intends to take advantage of certain exemptions from various reporting requirements.

The combined company's headquarter are located at 520 U.S. Highway 22, Suite 305, Bridgewater, New Jersey 08807.

ITEM 1A-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 AMZEEQ for the treatment of acne and our lead product candidate FMX103 for the treatment of rosacea.

We have invested a majority of our efforts and financial resources in the research and development of AMZEEQ for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older, which received approval from the FDA on October 18, 2019 and became available for prescribing on January 13, 2020, and FMX103 for the treatment of moderate-to-severe papulopustular rosacea in adults, for which we submitted an NDA, that was accepted for review by the FDA in October 2019. We plan to dedicate our resources toward (i) the continued commercialization efforts for AMZEEQ; (ii) pre-commercialization efforts for FMX103 in anticipation of FDA approval; and (iii) advancing our other pipeline candidates. The success of our business depends largely on our ability to successfully commercialize AMZEEQ and to obtain regulatory approval for and successfully commercialize 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.

Even though AMZEEQ has received FDA approval, and even if 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 though we have obtained FDA approval for AMZEEQ, and even if we obtain FDA approval for 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 AMZEEQ for the treatment of moderate-to-severe acne in patients 9 years of age and older and FMX103 for the treatment of moderate-to-severe rosacea in adults, as well as any other therapeutic indications that we may seek to pursue.

Moreover, if the treatment of acne with AMZEEQ 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 AMZEEQ, and, if approved, FMX103 and any of our other product candidates, 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;
- 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.
- 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 covered and adequately 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; and

We have limited commercial sales experience, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

Prior to the launch of AMZEEQ on January 13, 2020, we had not generated any revenues from the sale of our drug products. Successful commercialization of AMZEEQ or any future products is subject to many risks. Although many of our employees have commercialized products during their employment at other organizations, Foamix has not, as an organization, commercialized a product, and there is no guarantee that we will be able to do so successfully with AMZEEQ or any of our product candidates.

There are many factors that could cause commercialization of AMZEEQ or any future products to be unsuccessful, including a number of factors that are outside our control. The commercial success of AMZEEQ depends on, among other things, the extent to which patients and physicians accept and adopt AMZEEQ. For example, if the expected patient population is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take AMZEEQ, the commercial potential of AMZEEQ will be limited. In addition, we also do not know how physicians, patients and payors will respond to the pricing of AMZEEQ. Thus, significant uncertainty remains regarding the commercial potential of AMZEEQ. Moreover, our ability to effectively generate revenues from AMZEEQ will depend on our ability to, among other things:

- achieve and maintain compliance with regulatory and other requirements;
- create market demand for and achieve market acceptance of AMZEEQ through our marketing and sales activities and other arrangements established for the promotion of AMZEEQ;
- compete with other acne treatments (either in the present or in the future);
- train, deploy and support a qualified sales force;
- maintain and obtain agreements with third-party manufacturers that can produce commercial supplies of AMZEEQ at a scale sufficient to meet our anticipated demand and on terms acceptable to us and that can develop, validate and maintain commercially viable manufacturing processes that are compliant with current cGMP regulations, including our exclusive agreement with ASM for the supply of the finished product of AMZEEQ and our third party agreements with the suppliers of AMZEEQ's API;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- ensure that our entire supply chain efficiently and consistently delivers AMZEEQ to our customers;
- receive coverage and adequate reimbursement for AMZEEQ from commercial health plans and governmental health programs;
- successfully educate physicians and patients about the benefits, risks, administration and use of AMZEEQ;
- obtain acceptance of AMZEEQ as safe and effective by patients and the medical community;
- receive positive publicity related to AMZEEQ relative to the publicity related to our competitors' products; and
- maintain and defend our patent protection, seek additional protection and obtain regulatory exclusivity for AMZEEQ and our other product candidates.

Any disruption in our ability to generate revenues from the sale of AMZEEQ will have a material and adverse impact on our results of operations.

We are currently building our sales, marketing and distribution capabilities, and if we are unable to expand such capabilities, our business, results of operations and financial condition may be materially adversely affected.

In order to successfully market AMZEEQ, we must continue to build and develop our sales, marketing, distribution, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize AMZEEQ and may not become profitable.

AMZEEQ is a newly-marketed drug and, therefore, none of the members of our sales force has ever promoted AMZEEQ prior to its commercial launch. In addition, we must train our sales force to ensure that a consistent and appropriate message about AMZEEQ is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of AMZEEQ and its proper administration, our efforts to successfully commercialize AMZEEQ could be harmed, which would negatively impact our ability to generate product revenue.

Additionally, even after initial development of our sales force and the commercial launch of AMZEEQ, we will need to maintain and further develop our sales force, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, our ability to effectively commercialize AMZEEQ would be limited, and we would not be able to generate product revenues successfully. There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, any efforts to develop a sales and marketing organization would be subject to numerous risks, including, but not limited to, the following:

- recruiting and training a sales force is expensive and time consuming and could delay our product launch;
- we may be unable to recruit, retain or motivate adequate numbers of effective and qualified sales and marketing personnel;
- we may be unable to provide adequate training to sales and marketing personnel;
- our sales personnel may be unable to obtain access to physicians or convince adequate numbers of physicians to prescribe AMZEEQ;
- there may be unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- we may incur significant unexpected expenses if the commercial launch of AMZEEQ is delayed or does not occur for any reason.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our proposed products.

We have not obtained regulatory approvals to market FMX103 or our other pipeline product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize these product candidates.

The process of developing, obtaining regulatory approval for and commercializing FMX103 and our other product candidates is long, complex, costly and uncertain, and delays or failure can occur at any stage. Furthermore, the research, testing, manufacturing, labeling, marketing, sale and distribution of drugs are subject to extensive and rigorous regulation by the FDA. We are not permitted to market any of our product candidates in the United States until we receive approval of the applicable NDA from the FDA. To gain approval of an NDA or other equivalent regulatory approval, we must provide the FDA with clinical data that demonstrates the continued safety and efficacy of the product for the intended indication.

While we have received FDA approval to market AMZEEQ, we have not received formal regulatory clearance to market FMX103 from the FDA. Our other product candidates are at earlier stages of development and therefore subject to similar or even greater uncertainty and risk than FMX103.

Although we received positive Phase III clinical trial results for FMX103, the results of those clinical trials may be unsatisfactory to the FDA even if we believe those clinical trials were successful. The FDA may require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA 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 to provide regulatory approval.

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

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, including the NDA for our product candidate FMX103 for the treatment of moderate-to-severe papulopustular rosacea in adults, which was accepted for review in October 2019, and such delays could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If the FDA does not conclude that FMX103 satisfies the requirements under Section 505(b)(2) of the FDCA, or Section 505(b)(2), or if the requirements for FMX103 under Section 505(b)(2) are not as we expect, the approval pathway 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 have submitted an NDA for FMX103 under the FDA's 505(b)(2) regulatory pathway. The Hatch-Waxman Act added Section 505(b)(2) to the 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 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 FMX103, and complications and risks associated with this product candidate, 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 candidate, 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 candidate may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of AMZEEQ and certain other 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, and we may be required to certify against patents listed in the FDA's Orange Book. 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 FMX103, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if FMX103 is 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.

We may not receive market exclusivity for our product candidates under the Hatch-Waxman Act since our lead product candidates are based on an "old antibiotic" and therefore potential competitors may develop generic versions of our product(s) after launch that, if approved, could compete directly with our product(s) sooner than we expect.

Statutory 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 and ANDAs, including for a generic version of the drug product, for prescribed periods of time. During the exclusivity period, the FDA may not approve a Section 505(b)(2) application or ANDA to the extent it is subject to exclusivity, or in the case of exclusivity for a new chemical entity may not receive a Section 505(b)(2) application or ANDA. Changes to a drug resulting from new clinical studies (other than bioavailability studies) that were "essential to approval," and conducted or sponsored by the applicant, such as a new dosage form, strength, route of administration, dosing regimen or indication, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA or 505(b)(2) application for the change.

Drugs based on an "old antibiotic," such as minocycline, are subject to an additional limitation and will not receive three-year exclusivity for a "condition of use" that was approved before October 8, 2008. Prior to 2008, drugs based on an "old antibiotic" were not eligible for Hatch-Waxman Act exclusivity. In 2008, the Q1 Program Supplemental Funding Act of 2008 made drugs containing old antibiotics eligible for three-year exclusivity under certain conditions, but excluded from eligibility for that exclusivity any "condition of use" approved for such drugs before October 8, 2008. The statute does not define "condition of use" but the U.S. District Court has provided guidance in *Viropharma, Inc. v. Hamburg*, *898 F. Supp.2d* (District of Columbia, 2012). In *Viropharma*, the court held that a supplemental new drug approval for the drug Vancocin was not eligible for three-year exclusivity because the supplemental new drug application at issue did not constitute a "significant new use" for the drug. The court held that the "inclusion of more specific dosing information that was within the range specified in the prior label," "new instructions on monitoring patients' renal function," and "new instructions for the continuation of treatment in older patients" did not effect a "significant new use" but rather served only to "refine labeling regarding already approved conditions of use." The FDA also emphasized that had the company sought approval for a new indication or a new dosing regimen, it would have had to comply with other statutory requirements (including by providing new pediatric data), and that since the company did not have to provide the clinical data, it did not merit the three-year exclusivity for old antibiotics.

We believe that the clinical data submitted for our product candidates will satisfy the exclusivity requirements for old antibiotics. Our Phase III clinical trials for AMZEEQ provided new clinical (including new pediatric) data that supported a topical route of administration, a new dosing regimen and a significantly lower concentration of minocycline than the prior oral form. FMX103 is indicated for the treatment of moderate-to-severe papulopustular rosacea, which is a new indication for minocycline. While we believe that any clinical data submitted to support FMX103 and each of our other pipeline products containing an old antibiotic will provide the required new significant benefits and uses to qualify for the three-year non-patent exclusivity, if the FDA and the U.S. courts do not agree with us, the product candidate would not be protected by three-year exclusivity under the Hatch Waxman Act. While we would continue to be able to enforce our patents listed in the FDA's Orange Book against infringement by third-parties, including a 30-month or any further stay or injunction from a court during the pendency of litigation, the FDA could approve an ANDA for a generic version of our product and a company could launch the product at risk and we may not be able to obtain an injunction to prevent the launch, which would allow a generic into the market sooner than we expect. In addition, even if the FDA awards three-year exclusivity to each of these products, its scope will depend on how the FDA defines the exclusivity-protected change. If the FDA defines this change more narrowly than we anticipate, the three-year exclusivity could provide less protection against generic competition than expected. Moreover, even if we obtain three years marketing exclusivity an ANDA may be submitted at any time before the expiration of market exclusivity.

Because our Phase III clinical trials for AMZEEQ and FMX103 were not conducted head-to-head with the current standard of care drugs, we may not compare our results to those of existing drugs for promotional purposes, which may affect our sales and marketing efforts.

None of our Phase III clinical trials for AMZEEQ and FMX103 were conducted in head-to-head comparison with the drugs considered the current standard of care for the relevant indications, namely oral Solodyn for moderate-to-severe acne, and topical antimicrobials (such as Metrogel, generic metronidazole and Finacea) for rosacea. This means that none of the patient groups participating in these trials were or are being treated with the standard of care drugs alongside the groups treated with our product candidates.

The FDA generally requires adequate, well-controlled head-to-head clinical trials to support comparative claims regarding marketed products. As a result, we may not make promotional claims that compare AMZEEQ, FMX103 or any of our other product candidates that are commercialized in the future to the current standards of care or other competitor products which may negatively impact sales of our products.

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

Although we received FDA approval of AMZEEQ, we expect to continue to incur losses for the near future, which will delay our profitability. Moreover, it is possible that even if we succeed in developing and commercializing one or more of our other product candidates, we may never become profitable. Our near-term prospects, including our ability to finance our operations and generate revenues, depend on the successful commercialization of AMZEEQ and on the successful regulatory approval and commercialization of FMX103. The success of AMZEEQ, FMX103 and our other product candidates depends on a number of factors, many of which are beyond our control, including:

- the effectiveness of our marketing, sales and distribution strategy and operations;
- our ability to maintain, independently or via third parties, a commercially viable manufacturing process that is compliant with cGMP;
- our success in educating health care providers and patients about the benefits, administration and use of AMZEEQ and, if approved, FMX103 and our other product candidates;
- the FDA's acceptance of our parameters for regulatory approval relating to FMX103 and our other product candidates, including our proposed indications, primary endpoint assessments, primary endpoint measurements and regulatory pathways;
- the FDA's acceptance of the number, design, size, conduct and implementation of our clinical trials for our clinical-stage product candidates, our trial protocols and the interpretation of data from preclinical studies or clinical trials;
- the FDA's acceptance of the sufficiency of the data we collected from our preclinical studies and clinical trials to support the submission of an NDA without requiring additional preclinical or clinical trials;
- the FDA's willingness to schedule an advisory committee meeting in a timely manner to evaluate and decide on the approval of an NDA;
- the recommendation of the FDA 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 satisfaction with the NDA submission for FMX103 or our other product candidates;
- the prevalence and severity of adverse events associated with AMZEEQ, FMX103 and our other product candidates;
- the timely and satisfactory performance by third party contractors of their obligations in relation to our clinical trials and our manufacturing and supply of AMZEEQ and our product candidates;
- 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;
- our ability to take advantage of the 505(b)(2) regulatory pathway and obtain regulatory marketing exclusivity for our products under the Hatch-Waxman Act;
- our ability to create, pursue, obtain, protect and enforce our intellectual property rights with respect to AMZEEQ, FMX103 or our other product candidates;
- the prevalence and severity of signs and symptoms associated with AMZEEQ, FMX103 and our other product candidates;
- our ability to bring an action timely for patent infringement arising out of the filing of ANDAs by generic companies seeking approval to market generic versions of our products before the expiry of our patents;
- our ability to bring an action timely for patent infringement arising out of the filing of 505(b)(2) applications by companies seeking approval to market products before expiry of our patents; 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 AMZEEQ or our product candidates. Accordingly, we may not be able to generate sufficient revenues through the sale of AMZEEQ, FMX103 or our other product candidates to enable us to continue our business.

We may encounter delays in completing clinical trials for our 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 experienced significant delays in our Phase III clinical program for AMZEEQ, first due to quality control issues with certain active ingredients supplied to us by a third party and due to insufficient results in one of the co-primary endpoints, namely IGA treatment success, in one of the two initial Phase III trials, after which we conducted an additional Phase III clinical trial. Such difficulties may arise again in future trials for other indications and for our product candidates.

We rely on clinical 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 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 also 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, or by the FDA. 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 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.

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

To date, AMZEEQ and FMX103 have not been associated with 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. AMZEEQ and FMX103 have both been observed to have a generally favorable safety profile, with the most commonly reported adverse events related to upper respiratory tract infections, and there were no treatment-related serious adverse events reported. Nonetheless, upon commercialization of AMZEEQ, and, if approved, FMX103 or other product candidates, 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 AMZEEQ or one of our product candidates, a number of other potentially significant negative consequences could result, including:

- sales of the product may be more modest than originally anticipated;
- the FDA may suspend or withdraw its approval of the product;
- the FDA may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- the FDA may require us to issue specific communications to healthcare professionals, such as letters alerting them to new safety information about our product, changes in usage or other important information;
- the FDA 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;
- perception of our products by physicians and patients may be adversely affected; 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 or product candidate and could substantially increase commercialization costs or even force us to cease operations.

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

The FDA may also approve 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, including AMZEEQ, 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 if we discover previously unknown problems with any approved commercial products, manufacturers or manufacturing processes, we could be subject to administrative or judicially imposed sanctions or other setbacks, which could require us to take corrective actions, including to:

- 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.

We may decide not to continue developing or commercializing any of our product candidates at any time during development or of any of our products after approval, which would reduce or eliminate our potential return on investment for those product candidates or products.

We have in the past and may again in the future decide to discontinue the development of any of our product candidates in our pipeline or not to continue to commercialize any approved product. We may discontinue development of other product candidates for a variety of reasons, such as the appearance of new technologies that make our product less commercially viable, an increase in competition from generic or other competing products, changes in or failure to comply with applicable regulatory requirements, the discovery of unforeseen side effects during clinical development or after the approved product has been marketed or the occurrence of adverse events at a rate or severity level that is greater than experienced in prior clinical trials. If we discontinue a program in which we have invested significant resources, we will receive a limited return on our investment and we will have missed the opportunity to have allocated those resources to other product candidates in our pipeline that may have had potentially more productive uses.

If we are not successful in developing, acquiring regulatory approval for and commercializing additional product candidates beyond AMZEEQ 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 commercialization of AMZEEQ and on the potential approval of FMX103 for the treatment of moderate-to-severe rosacea, another key element of our strategy is to discover, develop and commercialize products based on our proprietary foam or other topical platforms to serve additional dermatology indications and therapeutic markets. We are seeking to do so through our internal research programs, but our resources are limited, and our current programs are primarily geared towards commercializing AMZEEQ and seeking regulatory approval for FMX103. We may also explore strategic collaborations for the development or acquisition of new products and product candidates, but we may not be successful in entering into such relationships. While we have received FDA approval for AMZEEQ and our NDA for FMX103 for the treatment of rosacea has been accepted by the FDA, all of our other potential product candidates remain in 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 may 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;
- creation of intellectual property rights, such as patents, which are necessary to protect our interests in a product candidate, can be challenging in relation to pharmaceutical formulations and their uses with known active pharmaceutical ingredients and generally used combinations of inactive ingredients approved by the FDA;
- intellectual property rights, such as patents, which are necessary to protect our interests in a product candidate, may be difficult to obtain or unobtainable or if obtained may be difficult to enforce or unenforceable;
- intellectual property rights, such as patents, may fail to provide adequate protection, may be challenged and one or more claims may be revoked or the patent may be held to be invalid; and
- intellectual property rights of third parties may potentially block our entry into certain markets, or make such entry economically impracticable.

AMZEEQ and, if approved, FMX103 will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration and expansion.

The approved indication of AMZEEQ is to treat inflammatory lesions of non-nodular moderate-to-severe acne in patients 9 years of age and older, and the expected indication of FMX103 is to treat moderate-to-severe papulopustular rosacea in adults. 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. AMZEEQ faces significant competition from other acne products, including oral drugs such as Seysara, Solodyn, Doryx, Dynacin, Acticlate and Minocin, and topical anti-acne drugs such as Aklief, 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 currently available to consumers. AMZEEQ and, if approved, FMX103 may also compete with non-prescription anti-acne and rosacea products and unapproved and off-label treatments.

There are also several potential competing products currently under development. One of such potential competing products is a topical gel suspension containing minocycline non-hydrochloride for the treatment of inflammatory skin disease, including acne and rosacea, developed by Hovione, a manufacturer of active pharmaceutical ingredients and drug product intermediates, which product candidate has recently completed Phase II clinical trials for the treatment of moderate-to-severe papulopustular rosacea and has obtained FDA input for the design of a planned Phase III clinical trial. Another such potential competing product is a topical hydrophilic gel containing minocycline hydrochloride for the treatment of acne, known as BPX-01, developed by BioPharmX Corporation, for which BioPharmX has completed Phase IIa and Phase IIb clinical trials and has obtained FDA input for the design of a planned Phase III clinical trial. BioPharmX has also announced positive results for its Phase IIb study for a topical minocycline gel named BPX-04 for the treatment of rosacea. In addition, Sol-Gel is developing topical drugs containing microencapsulated benzoyl peroxide for the treatment of rosacea and acne vulgaris and intends to submit an NDA for each candidate in 2020. If ultimately approved and launched in the U.S., these products would become direct competitors to AMZEEQ and FMX103.

To compete successfully in the acne and rosacea treatment markets, we will have to continue to demonstrate that AMZEEQ is safe and effective for the treatment of moderate-to-severe acne and to demonstrate that 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 United States. 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, if we partner with other companies in these markets and launch our products, we may face more competition in these markets than in the United States.

In addition, we may not be able to price AMZEEQ or, if approved, FMX103, 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 AMZEEQ or FMX103 successfully. Potential competitors may challenge, narrow, invalidate or seek to design around the claims of our granted patents or our patent applications, and such patents and patent applications may fail to provide adequate protection for our product candidates. 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.

Healthcare reforms by governmental authorities and related reductions in pharmaceutical pricing, reimbursement and coverage by third party payors may adversely affect our business.

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

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

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.

Significant developments that may adversely affect pricing in the United States include the enactment of federal healthcare reform laws and regulations, including the ACA and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Changes in the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third party payors. While healthcare reform legislation may have increased the number of patients who are expected to have insurance coverage for our product candidates, provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition.

Since its enactment, there have been judicial, Congressional and political challenges to certain aspects of the ACA. For example, President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On January 3, 2020, the U.S. House of Representatives filed a petition for a writ of certiorari with the U.S. Supreme Court. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling and petition will have on the status of the ACA. Although we cannot predict the form of any such replacement of the ACA may take, if any, or the full effect on our business of 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 United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

It is likely that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a pharmaceutical manufacturer’s products or additional pricing pressure.

It will be difficult for us to profitably sell AMZEEQ, 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 AMZEEQ, and, if approved, FMX103 and our other product candidates 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 AMZEEQ 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 United States 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 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, inter alia, 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 adversely affect 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 anticipate that we will continue to expend substantial resources for the foreseeable future for the commercialization of AMZEEQ and for pre-commercialization efforts related to FMX103. We also wish to continue the development of other indications and 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.

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 of the numerous risks and uncertainties associated with product development and commercialization, we are unable to reliably estimate the actual amounts necessary to successfully complete the development and commercialization of any of our product candidates.

Based on our current plans, we believe our existing cash and investments will be sufficient to fund our operating expenses and capital requirements into the second quarter of 2021. However, our operating plan may change as a result of many factors currently unknown to us. We may therefore 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 cost of commercialization activities for AMZEEQ, FMX103 or any of our other product candidates approved for sale, including marketing, sales and distribution costs;
- the degree and rate of market acceptance of AMZEEQ and any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- the results of the clinical trials of our product 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 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;
- 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 AMZEEQ or 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 creating, obtaining, protecting, defending and enforcing intellectual property, such as costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, litigation costs, including for patent infringement arising out of ANDA submissions by generic companies to manufacture and sell generic products or arising out of 505(2)(b) submissions, and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, approved products.

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 our establishment of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize AMZEEQ, FMX103 or any of our other product candidates.
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our 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 incurred significant losses since our inception and we anticipate that we will continue to incur losses in the near future.

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 $95.2 million, $74.2 million and $65.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $310.6 million and had a working capital surplus of $47.1 million. We expect to continue to incur losses, and we anticipate these losses may continue as we advance our commercialization efforts for AMZEEQ and as we continue our development of, and seek regulatory approvals for, FMX103 and our other product candidates.

We expect to rely on third parties to conduct some or all aspects of our drug product manufacturing, production research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our drug product manufacturing, production research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to these items, including manufacturing in the commercial context.

We have arrangements in place with two suppliers for the supply of the API of AMZEEQ and FMX103, and an exclusive supply agreement with ASM, for the manufacturing and supply of our finished product of AMZEEQ. Pursuant to the agreement, ASM has agreed to manufacture and supply all of our commercial needs for the products on an exclusive basis for a period of four years, subject to certain exceptions.

Our reliance on these third parties for manufacturing, research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for products that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical studies are conducted in accordance with the study plan and protocols, and that our products are manufactured in accordance with cGMP as applied in the relevant jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our drug products in accordance with cGMP, we will not be able to complete, or may be delayed in completing, the preclinical and clinical studies and manufacturing process validation activities required to support future IND submissions and approval of our product candidates, or to support commercialization of AMZEEQ and, if approved, FMX103 and our other product candidates. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us upon notice. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

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 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 the manufacture and commercial sale of AMZEEQ or our product candidates, if approved, and may disrupt and delay our clinical trials.

We may be forced to manufacture our product ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or failure to obtain marketing approval, or impact our ability to successfully commercialize our product or any future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product and product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We and the contract manufacturers for our product and product candidates are subject to extensive regulation. Some components of a finished drug product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product and product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of regulatory applications on a timely basis and where required, must adhere to the FDA's or other regulator's good laboratory practices and cGMP regulations enforced by the FDA or other regulator through facilities inspection programs. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product and potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or other marketing approval of the products may not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulators can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product and any future products, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure, validate and obtain approval of one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenues.

We expect to rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We also rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to assist us in conducting our clinical trials for our other product candidates. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's and other regulatory authorities' good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical studies to assure that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of clinical study participants are protected. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical studies may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical studies before approving any marketing applications.

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.

Supply interruptions may disrupt our inventory levels and the availability of our products and product candidates and cause delays in obtaining regulatory approval for our product candidates or harm our business by reducing our revenues.

We depend on a limited number of manufacturing facilities to manufacture our finished products and product candidates. Numerous factors could cause interruptions in the supply or manufacture of our products and product candidates, including:

- timing, scheduling and prioritization of production by our contract manufacturers or a breach of our agreements by our contract manufacturers;
- labor interruptions;

- changes in our sources for manufacturing;
- the timing and delivery of shipments;
- our failure to locate and obtain replacement suppliers and manufacturers as needed on a timely basis; and
- conditions affecting the cost and availability of raw materials.

If one of our suppliers or manufacturers fails or refuses to supply us with necessary raw materials or finished products or product candidates on a timely basis or at all, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. We may not be able to obtain active ingredients or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all.

Any interruption in the supply of finished products could hinder our ability to distribute finished products to meet commercial demand and adversely affect our financial results and financial condition.

With respect to our product candidates, production of product is necessary to perform clinical trials and successful registration batches are necessary to file for approval to commercially market and sell product candidates. Delays in obtaining clinical material or registration batches could adversely impact our clinical trials and delay regulatory approval for our product candidates.

We currently develop our clinical drug product candidates in our research and development facility located in Rehovot, Israel and through partnerships with external contract manufacturing organizations. If these facilities 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 could be materially harmed.

We currently research and develop our product candidates primarily in our laboratory located in Rehovot, Israel and through partnership with external contract manufacturing organizations. If these or any future facilities 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. 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 covering damage to our property and equipment and 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.

We face risks related to health epidemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial results.

In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. As of March 2020, that outbreak has led to numerous confirmed cases worldwide, including in the Unites States and other countries where we or our business partners conduct operations. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce. The future progression of the outbreak and its effects on our business and operations are uncertain. We are currently unaware of any disruptions to our business or any impact on our primary suppliers. In addition, we believe we have a sufficient amount of product in the trade and safety stock of our raw materials to support the current demand for AMZEEQ. However, if the outbreak of COVID-19 persists, we and our third-party contract manufacturers, contract research organizations and clinical sites may experience disruptions in supply of our product and product candidates and/or procuring items that are essential for our commercialization and research and development activities, including, for example, raw materials used in the manufacturing of our products and product candidates, medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, for which there may be shortages because of ongoing efforts to address the outbreak. Any negative impact that the outbreak has on the ability of our suppliers to provide materials for our product and product candidates or on retaining patients in our clinical trials could disrupt our commercialization efforts and clinical trial activities, which could adversely affect our ability to earn revenue, obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

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 as we commercialize AMZEEQ and any other product candidates that receive marketing approval. 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 AMZEEQ, 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.

Although we maintain product liability 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.

Our Credit Agreement subjects us to various financial and other restrictive covenants. These restrictions may limit our operational or financial flexibility and could subject us to potential defaults under our Credit Agreement.

On July 29, 2019, we entered into a Credit Agreement and Guaranty, or the Credit Agreement, with Foamix Pharmaceuticals Inc., lenders from time to time party thereto, the subsidiary guarantors from time to time party thereto, or the Subsidiary Guarantors, and Perceptive Credit Holdings II, LP, or Perceptive, as administrative agent, that provides a senior secured (including security on our intellectual property, which for example is registered against our patents and applications at the USPTO) delayed draw term loan facility in an aggregate principal amount of up to $50.0 million. The Credit Agreement contains financial and other restrictive covenants that limit the ability of us, Foamix Pharmaceuticals Inc. and the Subsidiary Guarantors, among other things, to incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions or changes to business activities; make certain investments or payments; or pay dividends. The Credit Agreement also contains certain financial covenants, including that we, Foamix Pharmaceuticals Inc. and the Subsidiary Guarantors must (1) maintain a minimum aggregate cash balance of $2.5 million; and (2) as of the last day of each fiscal quarter commencing on the fiscal quarter ending September 30, 2020, receive revenue for the trailing 12-month period in amounts set forth in the Credit Agreement, which range from $10.5 million for the fiscal quarter ending September 30, 2020 to $109.5 million for the fiscal quarter ending June 30, 2024.

The restrictive covenants in the Credit Agreement may limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that could be in our interest. Our ability to comply with these financial covenants can be affected by events beyond our control and we may not be able to do so. If we are unable to remain in compliance with the restrictive covenants of the Credit Agreement, then amounts outstanding thereunder may be accelerated and become due immediately. Any such acceleration could have a material adverse effect on our financial condition and results of operations.

Our debt obligations and any future debt obligations expose us to risks that could adversely affect our business, operating results, overall financial condition and may result in further dilution to our stockholders.

The Credit Agreement has a total borrowing capacity of up to $50.0 million, of which we have utilized $35.0 million as of December 31, 2019, and we may draw down the remaining $15.0 million prior to September 30, 2020 if we meet certain revenue targets as set forth in the Credit Agreement. Our current and any future indebtedness, including under the Credit Agreement, could have an adverse impact on our business or operations. For example, it could:

- limit our flexibility in commercializing AMZEEQ and the approval and marketing FMX103, as well as the development of our other pipeline product candidates;
- increase our vulnerability to both general and industry-specific adverse economic conditions; and
- limit our ability to obtain additional funds for working capital, capital expenditures, acquisitions, general corporate and other purposes.

Any current or future indebtedness that we incur, including under the Credit Agreement, will require us to make certain interest and principal payments. Our ability to make payments on this indebtedness depends on our ability to generate cash in the future. We expect to experience negative cash flow for the foreseeable future as we fund our operations and capital expenditures. There can be no assurance we will be in a position to repay this indebtedness when due or obtain extensions to the maturity date. In order to repay these obligations when due, we may be required to sell assets, to refinance all or a portion of such indebtedness or to obtain additional financing, including on terms that are not acceptable to us. If that additional financing involves the sale of equity securities or convertible securities, it would result in the issuance of additional shares of our capital stock, which would result in dilution to our shareholders.

Changes in interest rates could adversely affect our earnings and/or cash flows.

Loans under the Credit Agreement are made at variable rates that use LIBOR as a benchmark for establishing the interest rate. LIBOR is the subject of recent proposals for reform. On July 27, 2017, the United Kingdom's Financial Conduct Authority announced that it intends to stop persuading or compelling banks to submit LIBOR rates after 2021. These reforms may cause LIBOR to cease to exist, new methods of calculating LIBOR to be established or the establishment of an alternative reference rate(s). These consequences cannot be entirely predicted and could have an adverse impact on the market value for or value of LIBOR-linked loans that are due under the Credit Agreement. Changes in market interest rates may influence the financing costs and could reduce our earnings and cash flows.

If we fail to attract and keep senior management and key scientific and commercial personnel, we may be unable to successfully develop FMX103 or any of our other product candidates, conduct our clinical trials and commercialize AMZEEQ, or 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 and commercial 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 key sales personnel and 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 or successful commercialization of AMZEEQ, FMX103, if approved, or any of the clinical development 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.

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 our Phase I, II and III 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 are subject to various U.S. federal, state, local and foreign health care fraud and abuse laws, including anti-kickback, self-referral, false claims and fraud laws, health information privacy and security, and transparency laws and any violations by us of such laws could result in substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal, state, local and foreign health care fraud and abuse laws pertaining to our business, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers, patients and third-party payors are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government, states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, soliciting, receiving, or paying 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 goods or services for which payment may be made in whole or part by Medicare, Medicaid 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. The intent standard under the federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it, in order to have committed a violation. In addition, the ACA provides that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Additionally, many states have similar laws that apply to their state health care programs as well as private payors. Violations of the federal and state anti-kickback laws can result in exclusion from federal and state health care programs and substantial civil and criminal penalties.

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the FCA, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment from Medicare, Medicaid or other federal healthcare programs, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. Even where pharmaceutical companies do not submit claims directly to payors, they can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, activities relating to the reporting of wholesaler or estimated retail prices for pharmaceutical products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for such products, and the sale and marketing of such products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Private individuals or "whistleblowers" can bring FCA "qui tam" actions on behalf of the government and may share in recovered amounts. 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. Proof of intent to deceive is not required to establish liability under the civil False Claims Act.

- HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program, including any third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false statements relating to healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as "covered entities," and "business associates." Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates - independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office for Civil Rights, or the OCR, has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding $5 million. In addition, according to the United States Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 USC § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of prescription drugs, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), will extend the Sunshine Act to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level healthcare providers (with reporting requirements going into effect in 2022 for payments made in 2021). In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to physicians;

- analogous state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, and other states' laws addressing the pharmaceutical and healthcare industries, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and in some cases that may apply regardless of payor, *i.e.*, even if reimbursement is not available; state laws that require drug companies to comply with the industry's voluntary compliance guidelines (the PhRMA Code) and the applicable compliance program guidance promulgated by the federal government (HHS-OIG) or otherwise prohibit or restrict gifts or payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to drug pricing or payments and other transfers of value to healthcare providers or marketing expenditures and pricing information; and state laws related to insurance fraud in the case of claims involving private insurers;

- data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States, such as the European Union, which adopted the General Data Protection Regulation (GDPR), which became effective in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business; and

- State laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and may apply more broadly than HIPAA, thus complicating compliance efforts – for example, the California Consumer Privacy Act, or CCPA, which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted.

State and federal authorities have aggressively targeted pharmaceutical companies for alleged violations of these fraud and abuse laws 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. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private *qui tam* actions brought by individual whistleblowers in the name of the government. 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 or corporate integrity agreements that severely restrict the manner in which they conduct their business, including the requirement of additional reporting and oversight obligations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business and reputation. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we becomes subject to a corporate integrity agreement or consent decree, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

We are subject to various U.S. and foreign anti-bribery and anti-corruption laws, and any violations by us of such laws could result in substantial penalties.

The U.S. Foreign Corrupt Practices Act, or FCPA, and similar worldwide anti-bribery and anti-corruption laws generally prohibit companies and their intermediaries from offering, making or authorizing improper payments to government officials for the purpose of obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. 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 AMZEEQ, 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 AMZEEQ, or if approved, FMX103 or any of our other product candidates, 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 New 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 NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, 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 NIS against the dollar. For example, the NIS appreciated against the dollar by 7.8% in 2019, which appreciation was compounded by inflation at the rate of 0.6% that year, while in 2018 the NIS depreciated by 8.1% against the dollar, which depreciation was partly offset by inflation in Israel of 0.8% that year. 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.

Our 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 research and development facilities are located in Rehovot, Israel. In addition, some 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, certain countries, as well as certain companies and organizations, continue to participate in a boycott of Israeli businesses and businesses with large Israeli operations. Such boycott or other restrictive laws, policies or practices may have a material adverse effect on our business and financial condition in the future. In addition, our operations could be disrupted by the obligations of personnel to perform military reserve service.

Sanctions and other trade control laws create the potential for significant liabilities, penalties and reputational harm.

As a company transitioning to commercialization in the United States and overseas, we may be subject to national laws as well as international treaties and conventions controlling imports, exports, re-export and diversion of goods, services and technology. These include import and customs laws, export controls, trade embargoes and economic sanctions, denied party watch lists and anti-boycott measures (collectively "Customs and Trade Controls"). Applicable Customs and Trade Controls are administered by Israel's Ministry of Finance, the U.S. Treasury's Office of Foreign Assets Control (OFAC), other U.S. agencies and other agencies of other jurisdictions where we do business. Customs and Trade Controls relate to a number of aspects of our business, including most notably the sales of finished goods and API as well as the licensing of our intellectual property, as provided above. Compliance with Customs and Trade Controls has been the subject of increasing focus and activity by regulatory authorities, both in the United States and elsewhere, in recent years. Although we have policies and procedures designed to address compliance with Customs and Trade Controls, actions by our employees, by third-party intermediaries (such as distributors and wholesalers) or others acting on our behalf in violation of relevant laws and regulations may expose us to liability and penalties for violations of Customs and Trade Controls and accordingly may have a material adverse effect on our reputation and our business, financial condition and results of operations.

Lawsuits that have been filed in connection with the Merger, the outcome of which are uncertain, could require Menlo and Foamix to incur significant costs and suffer management distraction.

Securities litigation or other shareholder litigation frequently follows the announcement of certain significant business transactions, such as the announcement of a business combination transaction. In connection with the Merger, purported shareholders of Foamix filed lawsuits against the company and members of the Foamix board of directors and some lawsuits named Menlo and Merger Sub as additional defendants. See "Item 3—Legal Proceedings" for a description of the lawsuits. Even if the lawsuits are without merit, as the defendants believe these lawsuits to be, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on the combined company's liquidity and financial condition.

Our disclosure controls and procedures and our systems to implement such disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and

recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Our Intellectual Property

If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our launched product AMZEEQ, to our Phase III product candidate 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, trademarks, confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to our launched product AMZEEQ, to our Phase III product candidate FMX103 and to 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 various patent claims, or by using formulations from expired patents 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 regulatory and/or 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 various granted patents related to AMZEEQ and FMX103 in the United States, which are expected to remain in effect until 2030. We also have an issued patent in the United States related to AMZEEQ that expires in September 2037. 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 patents granted claiming compositions of matter relating to AMZEEQ and FMX103 in each of the following international markets Australia, Canada, Great Britain, Israel, and Mexico and we have patent applications claiming compositions of matter relating to AMZEEQ and FMX103 pending in Canada, the European Union, India and Mexico.

As of December 31, 2019, we had over 200 granted patents and over 40 patent applications pending worldwide covering our various topical delivery 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 or held unenforceable by a court. Competitors and others in the field of topically-administered therapies comprising an active ingredient in foam and other presentations 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 or words 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, or the scope of the claims of patent applications that do issue may be too narrow or inadequate to protect our competitive advantage. Pending applications may be challenged during prosecution by the submission of third-party observations or pre-grant oppositions. Such observations may result in the scope of claims being narrowed or rejected or the application may be refused. Also, our granted patents may be subject to challenges or construed in a way that may not provide adequate or any 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 USPTO, may be subject to review, reexamination and other challenges. Changes to the U.S. patent laws 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 our launched product AMZEEQ, to FMX103 or any of our other product candidates are challenged, it could put one or more patents at risk of being invalidated, or interpreted narrowly and threaten our competitive advantage for AMZEEQ, 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 products and or product candidates or prevent others from designing around and or challenging 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 time consuming and may or may not be successful, which could also have a material adverse effect on the commercial potential for AMZEEQ, FMX103 and any of our other product candidates.

If we encounter challenges to our patent claims in relation to AMZEEQ and we are not ultimately able to defend them the period of time during which we will be able to market AMZEEQ may be reduced.

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

Since patent applications in the United States 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 AMZEEQ, to our Phase III product candidate FMX103, or to 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 United States 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, or AIA, 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. Until recently, a lower evidentiary standard was applied in certain USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim. Under the new final rule, effective for petitions filed on or after November 13, 2018, the USPTO Patent Trial and Appeal Board (PTAB) is to apply the same claim construction standard applied by civil courts under 35 USC §282(b) in *IPR*, post-grant review, and the transitional program for covered business method patents proceedings. The impact this may have in practice on the use and outcome of USPTO proceedings is uncertain. Because of lower costs and the fact that USPTO statistics indicate that a high rate of challenged claims are being invalidated in these USPTO procedures, they may continue to be a popular and effective means of challenging patents.

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 actions or counterclaims against us, and our competitors have intellectual property of their own, some of which include substantial patent portfolios. 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 held not to be infringed, or one or more of our patent applications may 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 additionally rely on trade secret protection and confidentiality agreements to protect proprietary know-how that we consider may be preferably maintained as a trade secret rather than the subject of a patent application. 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. We also enter into and rely on, where appropriate, common interest agreements to protect privileged confidential information.

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 accidental or 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. Although we make efforts to protect our trade secrets and other confidential information we cannot be certain that all parties that gain access to our proprietary information or who may be involved in the development of our intellectual property have entered into written confidentiality agreements or that such agreements will be sufficiently protective or that they will not be breached. 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.

Cybersecurity disruptions may impact our business operations if it becomes a target for such activities.

We may be subject to attempted cybersecurity disruptions from a variety of threat actors. If our systems for protecting against cybersecurity disruptions prove to be insufficient, our employees or third parties could be adversely affected. Such cybersecurity disruptions could cause damage or destroy assets, compromise business systems, result in proprietary information and trade secrets being altered, lost or stolen; result in employee or third-party information being compromised, or otherwise disrupt business operations. Significant costs to remedy the effects of such a cybersecurity disruption may be incurred by us, as well as in connection with resulting regulatory actions and litigation, and such disruption may harm relationships with third parties and impact our business reputation.

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 United States and in 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 one or more of legislative action to change statutory patent law, rule changes and practice directions issued by National Patent Offices, or court action that may reinterpret, limit or expand on existing law in ways affecting the scope or validity of granted patents. Particularly in recent years in the United States, 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 emulsion 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 or continue 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 and we may as a result have little or no control or say in any proceedings concerning them. In addition, any proceedings against our technology could impact any or all of our licensees, and we may be considered or found to 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 or rosacea and other indications have developed large portfolios of patents and patent applications relating to our business. In particular, there are patents and pending patent applications held by third parties that relate to formulations with minocycline-based and doxycycline-based products and to methods of treatment with minocycline-based and doxycycline-based products for indications we are pursuing with AMZEEQ, our Phase III product candidate FMX103 and our other such-based product candidates. There may be granted patents with claims that could be asserted against us in relation to such products or 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 may be 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 AMZEEQ, FMX103 or any of our other product candidates or activities. We may fail to identify applications and granted patents that may be asserted against us in relation to AMZEEQ, our Phase III product candidate FMX103 or any of our other product candidates or activities. Searches and analyses undertaken may miss or not uncover all potential and future threats. 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. These third parties could include non-practicing entities that have no relevant products or revenue. 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 or 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. In some jurisdictions, third party observations or pre-grant oppositions may be filed.The cost and burden 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, confidential information, 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 secure registrations and protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify "Foamix" and have registered these trademarks in the United States and Israel. We own the trademarks "AMZEEQ" and "MST" that identify our FDA approved topical product for acne vulgaris and its delivery technology and we have filed applications for these trademarks in the United States and in some other jurisdictions including Israel. We also own and have filed applications for trademarks in the United States that represent the logo used in connection with AMZEEQ, and the proposed logo(s) and commercial name(s) of our phase III drug product candidate.

Applications for trademarks may be rejected during prosecution and we may be unable to overcome such proceedings or we may have to narrow or limit the scope of the applications. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings or we may have to narrow or limit their scope.

In the US the FDA evaluates and must approve any trademark we propose to use with products for which we seek regulatory approval. Selecting a product trademark can be an expensive process. If the FDA objects to proposed trademarks this could delay regulatory approval and we may be required to expend significant resources in an effort to identify suitable substitutes that would qualify as a registerable trademark, not infringe any existing third party trademark rights and be acceptable to the FDA.

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, as well as 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 or method at issue on the grounds that our patent claims do not cover its technology or method or that the factors necessary to grant an injunction against an infringer are not satisfied.

We have received notice letters of ANDAs submitted for drug products that are generic versions of Finacea foam and we are involved in lawsuits to protect and enforce our patents, which are expensive, time consuming and may be unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and may be unsuccessful in whole or part. The infringing party may deny any infringement or challenge the patents as invalid or unenforceable. Litigation proceedings may also fail, and even if successful, they may result in substantial costs and distraction of our management and other employees.

For example, Paragraph IV Certification Notice Letters from Taro dated December 20, 2018 and January 18, 2019, were received in connection with Finacea foam. A Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Orange Book is allegedly invalid, unenforceable or will not be infringed by an ANDA product. In the case at hand, the letters were directed against several of our U.S. patents and stated that Taro had submitted to the FDA an ANDA for an azelaic acid foam composition which is a generic version of Finacea foam.

Pursuant to our licensing agreement with LEO, this litigation is in the sole control of LEO. Complaints were filed against Taro with the U.S. District Court for the District of Delaware, asserting, among other things, that Taro had infringed our patents, as listed in its Paragraph IV Notice Letters, by seeking FDA approval to manufacture and sell a generic version of Finacea prior to expiration of these patents. Since the complaint was filed within the 45-day period required under the Hatch-Waxman Act, a 30-month stay will preclude Taro from receiving final FDA approval of a generic version of Finacea prior to June 2021, unless a court enters judgment that the patents are invalid or not infringed.

Although we are currently unable to predict the outcome of the litigation, substitution of Finacea in favor of generic versions has the potential to have a negative impact on future commercialization of Finacea and to result in a loss of license revenue. Furthermore, in any infringement proceeding, a court may decide that a patent of ours, or one or more claims of such patent, is not valid or is unenforceable, or may refuse to stop the other party from using the supposedly infringing technology on the grounds that our patents, or one or more claims of such patents, do not cover such technology. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could also put one or more of our pending patent applications at risk of not issuing. There can be no assurance that our product candidates will not be subject to the same risks.

We have also entered into license agreements with other commercial partners for the development and commercialization of products with active ingredients other than azelaic acid that license one or more of the patents listed in the FDA's Orange Book for Finacea foam, or a family member thereof. Whilst these license agreements are not considered material to our main business, an adverse result may put at risk the development and commercialization of any of these licensed products.

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 or other proceedings, may result in substantial costs and distraction to our management. Moreover, proceedings may be appealed and obtaining a final resolution can take a long time and substantial resources. 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 and extent 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 or most countries throughout the world would be prohibitively expensive. We primarily file patent applications in the United States 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 United States are generally significantly less extensive than those in the United States. 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 United States, 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 United States, or from selling or importing products made using our inventions in and into the United States 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 United States. 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 or issue proceedings 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 and practice.

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.

ITEM 1B - UNRESOLVED STAFF COMMENTS

None.

ITEM 2 - PROPERTIES

Our facilities in Israel, which house our research and developments laboratories, are located in the Weizmann Science Park in Rehovot, Israel. We currently lease approximately 2,199 square meters under a lease that expires in December 31, 2020.

Our executive offices in the United States are located in Bridgewater, New Jersey. We currently lease approximately 15,000 square feet of office space under a lease that expires on August 31, 2022. We have an option to extend our existing lease for an additional three years on similar conditions.

We believe that our current office space and facilities in Israel and the United States are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future growth.

ITEM 3 - LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings relating to claims that we consider to be arising from the ordinary course of our business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business.

Litigation related to the Merger

On December 11, 2019, a purported Foamix shareholder filed a putative class action lawsuit in the United States District Court for the District of Delaware against Foamix, the members of the Foamix Board, Menlo and Merger Sub, claiming generally that the joint proxy statement/prospectus issued in connection with the Merger omitted material information in violation of Sections 14(a) and 20(a) of the Exchange Act. The action, captioned Sabatini v. Foamix Pharmaceuticals Ltd., et al., Case No. 1:19-cv-02257 (D. Del.), or the Sabatini Action, purports to be brought on behalf of all public shareholders of Foamix, excluding defendants and certain affiliated persons or entities, and seeks, among other things, to enjoin consummation of the Merger, or alternatively rescission or rescissory damages; to compel the individual defendants to disseminate a joint proxy statement/prospectus that does not contain any untrue statements of material fact and that states all material facts required in it or necessary to make the statements contained therein not misleading; a declaration that defendants violated Sections 14(a) and/or 20(a) of the Exchange Act; and an award of costs, including attorneys' and experts' fees and expenses.

On December 12 and 17, 2019, respectively, two purported Foamix shareholders filed lawsuits in the United States District Court for the District of New Jersey (the "New Jersey District Court") and the United States District Court for the Southern District of New York (the "Southern District of New York District Court") against Foamix and the members of the Foamix Board. The actions, captioned Wang v. Foamix Pharmaceuticals Ltd., et al., Case No. 19-21316 (D.N.J.), or the Wang Action, and Simms v. Foamix Pharmaceuticals Ltd., et al., Case No. 1:19-cv-11529 (S.D.N.Y.), or the Simms Action, each purport to be brought on behalf of the named plaintiff only and allege substantially similar claims and seek substantially similar relief as the Sabatini Action, as well as an accounting of damages allegedly suffered by the plaintiff.

On December 18, 2019, a purported Foamix shareholder filed a putative class action lawsuit in the New Jersey District Court against Foamix, the members of the Foamix Board, Menlo and Merger Sub, alleging generally claims for breach of fiduciary duty, aiding and abetting breaches of fiduciary duty, and violations of Sections 14(a) and 20(a) of the Exchange Act. The action, captioned Wilson v. Foamix Pharmaceuticals Ltd., et al., Case No. 3:19-cv-21563 (D.N.J.), or the Wilson Action, purports to be brought on behalf of all public shareholders of Foamix, excluding defendants and certain affiliated persons or entities, and alleges, among other things, that certain members of the Foamix Board and management are conflicted because they will receive unique benefits in connection with the Merger, that the Merger Agreement contains preclusive deal protection provisions, that the disclosures issued in connection with the Merger are false and misleading, and that the Merger consideration is inadequate. The Wilson Action seeks, among other things, to enjoin the Merger, or alternatively rescission or rescissory damages; a declaration that the Merger Agreement was entered into in breach of fiduciary duty and is therefore invalid and unenforceable; an order directing the individual defendants to commence a sale process for Foamix and obtain a transaction; an accounting of damages allegedly suffered by plaintiff and the putative class; and an award of costs, including attorneys' and experts' fees and expenses.

On December 20, 2019, a purported Foamix shareholder filed a lawsuit in the Southern District of New York District Court against Foamix and the members of the Foamix Board. The action, captioned Miller v. Foamix Pharmaceuticals Ltd., et al., Case No. 1:19-cv-1169 (S.D.N.Y.), or the Miller Action, purports to be brought on behalf of the named plaintiff only and alleges substantially similar claims and seeks substantially similar relief as the Sabatini, Wang, Simms and Wilson Actions.

On January 7, 2020, a purported shareholder of Foamix filed a lawsuit against Foamix and the members of the Foamix Board in the United States District Court for the District of New Jersey, alleging that the joint proxy statement/prospectus issued in connection with the Merger omitted material information in violation of Section 14(a) and Section 20(a) of the Exchange Act and Rule 14a-9 promulgated thereunder. The action, captioned Bushansky v. Foamix Pharmaceuticals Ltd., et al., Case No. 3:20-cv-00256 (D.N.J.), or the Bushansky Action, purports to be brought on behalf of the named plaintiff only and seeks, among other things, injunctive or other equitable relief, including to enjoin consummation of the Merger, or alternatively rescission or rescissory damages, a declaration that the defendants violated Sections 14(a) and/or 20(a) of the Exchange Act, and an award of costs, including attorneys' and experts' fees and expenses.

On January 21, 2020, a purported shareholder of Foamix filed an individual action against Foamix and the Foamix Board in the United States District Court for the District of New Jersey under the caption Nam v. Foamix Pharmaceuticals Ltd., et al., Case No. 3:20-cv-00670 (D.N.J.), (the "Nam Action" and together with the Sabatini, Wang, Simms, Wilson, Miller and Bushansky Actions, the "Lawsuits") . The Nam Action generally claims that the joint proxy statement/prospectus issued in connection with the Merger omitted material information in violation of Sections 14(a) and 20(a) of the Exchange Act. The Nam Action seeks, among other things, injunctive relief to prevent consummation of the Merger, rescission or rescissory damages in the event the Merger is consummated, a declaration that defendants violated Sections 14(a) and/or 20(a) of the Exchange Act, costs, including attorneys' fees and such other and further relief as the court may deem just and proper. In addition, the Nam Action requests an order directing the individual defendants to disseminate a proxy statement that does not contain any untrue statements of material fact and that states all material facts necessary to make the statements contained therein not misleading.

Foamix and the other defendants believe the Lawsuits are without merit and intend to defend vigorously against all claims asserted.

ITEM 4 - MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5 - MARKET FOR REGISTRANT'S ORDINARY SHARES, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our ordinary shares were previously listed on Nasdaq under the symbol "FOMX" since September 17, 2014. On the Effective Date, each ordinary share was converted into 0.5924 of a share of Menlo common stock and one CSR. As of the Effective Date, we are a wholly-owned subsidiary of Menlo. Accordingly, our ordinary shares are no longer listed on the Nasdaq.

ITEM 6 - 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, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017 have been derived from, and should be read in conjunction with, our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report. The selected financial data as of December 31, 2017, 2016 and 2015 and for the years ended December 31, 2016 and 2015 have been derived from our audited consolidated financial statements 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 7 - Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Annual Report.

Consolidated Statement of Operations Data

	Year ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands of U.S. dollars, except loss per share)				
Statements of operations data:					
Revenues	$ 443	$ 3,595	$ 3,669	$ 5,527	$ 849
Cost of revenues[1]	-	-	13	59	70
Gross profit	443	3,595	3,656	5,468	779
Operating expenses:					
Research and development[1]	51,202	64,474	57,779	25,897	10,680
Selling, general and administrative[1]	45,114	14,013	11,491	9,221	7,029
Total operating expenses	96,316	78,487	69,270	35,118	17,709
Operating loss	95,873	74,892	65,614	29,650	16,930
Net loss	$ 95,178	$ 74,163	$ 65,715	$ 29,336	$ 16,517
Loss per share basic and diluted	1.66	1.70	1.76	0.91	0.58

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

	Year ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands of U.S. dollars)				
Cost of revenues	$ -	$ -	$ 2	$ 3	$ 2
Research and development	1,564	2,054	1,711	1,135	588
Selling, general and administrative	3,331	3,266	2,453	1,774	1,187
Total share-based compensation	$ 4,895	$ 5,320	$ 4,166	$ 2,912	$ 1,777

Consolidated Balance Sheet Data

	As of December 31,				
	2019	2018	2017	2016	2015
Balance sheet data:	(in thousands of U.S. dollars, other than number of shares)				
Cash and investments[1]	$ 73,366	$ 99,385	$ 76,412	$ 130,988	$ 103,779
Working capital[2]	47,088	90,699	59,276	111,730	53,091
Total assets	81,159	103,731	80,254	135,635	105,245
Total long-term liabilities	34,258	1,081	1,425	379	385
Total shareholders’ equity	17,575	92,182	68,601	129,985	100,802
Capital shares	$ 2,659	$ 2,331	$ 1,576	$ 1,561	$ 1,284
Number of ordinary shares	61,580,544	54,351,140	37,498,128	37,167,791	30,639,134

(1) Cash and investments include cash and cash-equivalents, restricted cash, bank deposits, marketable securities and restricted marketable securities.

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

ITEM 7 - MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this report. 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 report, particularly in the section entitled “Item 1A-Risk Factors”.

We have omitted discussion of the earliest of the three years covered by our consolidated financial statements presented in this Annual Report because that disclosure was already included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019. You are encouraged to reference Part II, Item 7, within that report, for a discussion of our financial condition and result of operations for the year ended December 31, 2018 to the year ended December 31, 2017.

Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies in dermatology. Utilizing our expertise in the development of topical minocycline, we are working to develop and commercialize topical drugs for dermatological therapy, including the first topical minocycline products in the United States. On October 18, 2019, the FDA approved our first drug product, AMZEEQ™ (minocycline) topical foam, 4%, formerly known as FMX101 ("AMZEEQ"), a once-daily topical antibiotic for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older. AMZEEQ is the first topical minocycline to be approved by the FDA for any condition. AMZEEQ became available for prescribing on January 13, 2020.

On November 10, 2019, we entered into the Merger Agreement with Menlo and Merger Sub whereby Merger Sub agreed to merge with and into Foamix, with Foamix continuing as the surviving corporation and a wholly-owned subsidiary of Menlo. Menlo, which completed its initial public offering in January 2018 and is listed on the Nasdaq Global Select Market under the symbol "MNLO", is a late-stage biopharmaceutical company focused on the development and commercialization of serlopitant, an NK1 receptor antagonist given as a once-daily oral tablet for the treatment of pruritus, or itch, associated with various conditions such as prurigo nodularis ("PN") and psoriasis. Menlo's clinical development program for serlopitant includes two ongoing Phase III clinical trials for the treatment of pruritus associated with PN and a Phase III-ready clinical program for the treatment of pruritus associated with psoriasis. On March 9, 2020 (the "Effective Date"), the Merger was completed and Foamix is now a wholly-owned subsidiary of Menlo. Foamix will cease to be a reporting company as of March 19, 2020 and all future filings of the combined company will be made by Menlo.

On the Effective Date, each ordinary share of Foamix was exchanged for 0.5924 shares of common stock of Menlo (the "Exchange Ratio"). In addition, on the Effective Date, Foamix shareholders received one contingent stock right (a "CSR") for each Foamix ordinary share held by them. The CSRs are governed by the Contingent Stock Rights Agreement (the "CSR Agreement"), dated as of March 9, 2020, by and between Menlo and American Stock Transfer & Trust Company, LLC, and represent the non-transferable contractual right to receive shares of common stock of Menlo if specified events occur within agreed time periods. Pursuant to the CSR Agreement, each CSR may become convertible upon the occurrence of the events described below, and, if so converted, will entitle its holder to receive from Menlo additional shares of Menlo common stock. The CSR events relate to Menlo's Phase III PN Trials. The CSRs may become convertible and additional shares of Menlo common stock may become payable to the rights agent, for subsequent distribution to the holders of the CSRs, upon the occurrence of the following events:

- if, on or prior to May 31, 2020, the Efficacy Determination reports that proof of statistically significant superiority of serlopitant treatment over placebo treatment on the primary endpoint, as set out in the Merger Agreement ("Serlopitant Significance"), was achieved in one Phase III PN Trial but was not achieved (or has not been determined) in the other Phase III PN Trial, each CSR will be converted into 0.6815 shares of Menlo common stock pursuant to the terms and conditions of the CSR Agreement. Following such Efficacy Determination, the effective Exchange Ratio in the Merger will be 1.2739 shares of Menlo common stock for each Foamix ordinary share, increasing the former Foamix shareholders' ownership of the outstanding share capital of the combined company to approximately 76% and correspondingly decreasing the pre-Merger Menlo stockholders' ownership of the outstanding share capital of the combined company to approximately 24%, each calculated on a fully diluted basis (with such percentages calculated as if the CSR conversion to additional shares occurred on the Effective Date); and

- if, on or prior to May 31, 2020, the Efficacy Determination reports that Serlopitant Significance was not achieved in either of the Phase III PN Trials, or if the Efficacy Determination has not been delivered on or before May 31, 2020, each CSR will be converted into 1.2082 shares of Menlo common stock pursuant to the terms and conditions of the CSR Agreement. Following such Efficacy Determination, the effective Exchange Ratio in the Merger will be 1.8006 shares of Menlo common stock for each Foamix ordinary share, increasing the former Foamix shareholders' ownership of the outstanding share capital of the combined company to approximately 82% and correspondingly decreasing the pre-Merger Menlo stockholders' ownership of the outstanding share capital of the combined company to approximately 18%, each calculated on a fully diluted basis (with such percentages calculated as if the CSR conversion to additional shares occurred on the Effective Date).

If the Efficacy Determination reports that Serlopitant Significance was demonstrated in both Phase III PN Trials, the CSRs will automatically be terminated, and their holders will not be entitled to any additional shares of Menlo common stock pursuant to the CSR or the CSR Agreement. The effective Exchange Ratio in the Merger will remain 0.5924 shares of Menlo common stock for each Foamix ordinary share and former Foamix shareholders will maintain their ownership of approximately 59% of the outstanding share capital of the combined company, with the Menlo stockholders owning the remaining 41% of the outstanding share capital of the combined company, each calculated on a fully diluted basis.

In October 2019, we announced that the FDA accepted our NDA and set a target Prescription Drug User Fee ACT, or PDUFA, action date of June 2, 2020 for our late-stage drug product candidate, FMX103 (1.5% minocycline foam), for the treatment of moderate-to-severe papulopustular rosacea in adults. In November 2018, we announced that both of our Phase III clinical trials for FMX103 (Studies FX2016-11 and FX2016-12) met each of their co-primary endpoints, demonstrating a statistically significant reduction in inflammatory lesion counts and IGA treatment success, as assessed by Investigator's Global Assessment, or IGA, scores of approximately 50% from baseline. There were very few reported adverse events and no treatment-related serious adverse events observed in these Phase III clinical trials, as well as in the 40-week open label safety extension (Study FX2016-13) that was completed in February 2019. We cannot provide any assurances or predict with any certainty the schedule for which we will receive approval for FMX103, if at all.

Both AMZEEQ and FMX103 were developed using our Molecule Stabilizing Technology (MST™) vehicle, a proprietary foam platform designed to optimize the topical delivery of minocycline, an active pharmaceutical ingredient, or API, that was commercially available only in oral form until the FDA's approval of AMZEEQ.

In addition, we have proprietary delivery technologies in development that enable topical delivery of other APIs, each having unique pharmacological features and characteristics designed to keep the API stable when delivered and directed to the target site. We believe our MST vehicle and other topical delivery platforms may offer significant advantages over alternative delivery options and are suitable for multiple application sites across a range of conditions.

Our corporate strategy is to develop and solidify a commercial presence in acne and rosacea by commercializing our drug product AMZEEQ and by obtaining FDA approval for our late-stage drug product candidate FMX103, in the United States. We are also seeking to enhance our longer-term commercial potential by identifying and advancing additional product candidates through our internal development efforts, our entry into potential research collaborations or in-licensing arrangements, or our acquisition of additional products or technologies or product candidates that complement our current product portfolio.

We are currently developing a pipeline of other innovative product candidates to enhance our minocycline platform, including FCD105, a topical combination foam for the treatment of moderate-to-severe acne vulgaris, comprising minocycline 3% and adapalene 0.3%. In September 2019, we announced that the first patient was enrolled in our Phase II clinical trial (Study FX2016-40) to evaluate the efficacy and safety of FCD105. In November 2019, we announced that enrollment had been completed for this clinical trial, and we expect topline data from this Phase II clinical trial in the second quarter of 2020. Pending a successful development program, we intend to file an NDA for FCD105 under the FDA 505(b)(2) regulatory pathway, which is the same regulatory pathway we have pursued for AMZEEQ and are pursuing for FMX103.

To date, only one of our products, AMZEEQ, has been approved by the FDA, and we have only submitted one additional product candidate, FMX103, for approval by regulatory authorities. We do not currently have rights, other than for AMZEEQ, and those under our license agreement with LEO to any products that have been approved for marketing in any territory. We have financed our operations primarily through private and public placements of our ordinary shares, debt, warrants and through fees, cost reimbursements and royalties received from our licensees. We have incurred significant losses since our inception in 2003. Our accumulated deficit at December 31, 2019 was $310.6 million and our net loss for the year ended December 31, 2019 was $95.2 million. A substantial amount of our net losses resulted from costs incurred in connection with our research and development programs and clinical trials and from general and administrative costs associated with our operations. The net losses and negative operating cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate offsetting revenue, if any. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public and private equity offerings, debt or other structured financings, and entry into strategic collaborations. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our development programs or commercialization efforts. We will need to generate significant revenue to achieve and sustain profitability, and we may never be able to do so.

Revenues

As of December 31, 2019, we have not generated any revenues from sales of AMZEEQ, FMX103 or any of our other product candidates. During 2019 we were engaged in pre-launch sales and marketing planning activities and other pre-commercialization efforts in order to support the commercialization of AMZEEQ in the United States. We received FDA approval for AMZEEQ on October 18, 2019 and launched AMZEEQ in the United States on January 13, 2020. As a result, we expect to commence generating revenues from sales of AMZEEQ in the first half of 2020. We will not commercially launch FMX103 or other product candidates in the U.S. or generate any revenues from sales of any of our product candidates unless and until we obtain marketing approval. Our ability to generate revenues from sales will depend on the successful commercialization of AMZEEQ, and, if approved, FMX103 and any other product candidates.

As of December 31, 2019, we generated cumulative revenues of approximately $32.2 million under development and license agreements, of which approximately $18.4 million were development service payments, approximately $3.1 million were contingent payments and $10.7 million were royalty payments. The royalties were paid in relation to Finacea, the prescription foam product that we developed in collaboration with Bayer, which later assigned it to LEO. Our total revenues for the year ended December 31, 2018 was $3.6 million. Our total revenues for the year ended December 31, 2019 fell to $0.4 million due to the ongoing suspension of the manufacturing of Finacea by LEO, following inadequate supply of quality-compliant batches of the API used in such product, as described above in "Item 1 – Business Development and License Agreements." We may become entitled to additional contingent payments, subject to achievement of the applicable clinical results by our other 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%.

Cost of Revenues

There was no cost of revenues for the years ended December 31, 2019 and 2018, as revenues in both years consisted almost entirely of royalties, which do not bear related cost of revenue.

We expect to incur cost of revenue as we begin the serial production of AMZEEQ and we expect our cost of revenues to grow along with the growth of our sales and inventory needs.

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 to incur significant research and development costs in the foreseeable future, assuming 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 for our product pipeline. 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 AMZEEQ, FMX103 and FCD105. From January 1, 2007 until December 31, 2019, we cumulatively spent approximately $220.5 million on research and development of AMZEEQ, FMX103, FCD105 and our other product candidates. Our total research and development expenses for the years ended December 31, 2019 and 2018 were approximately $51.2 million and $64.5 million, respectively. We charge all research and development expenses to operations as they are incurred.

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
- other costs associated with preclinical and clinical activities and regulatory operations.

The successful development of our product candidates, other than FMX103, is highly uncertain. While we have filed an NDA for FMX103, we cannot provide any assurances that we will receive approval from the FDA. 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; and
- 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;

A change in the outcome of any of these variables with respect to the development of our product candidates could result in a significant change in the costs and timing associated with their development. For example, if the FDA was 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 time and financial resources on the completion of the clinical development.

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 $0.5 million received from the Israel-U.S. Bi-national Industrial Research and Development Foundation, or BIRD, in 2008, which was fully repaid in 2016. Accordingly, we are not subject to the provisions of the Law for Encouragement of Research and Development in the Industry, 5744-1984, nor to any directives issued by the Israel Innovation Authority, previously known as the Office of the Chief Scientist of the Ministry of Economy.

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 office space, 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, maintaining, and defending patents and other intellectual property.

We expect that our selling general and administrative expenses will increase due the commercialization of AMZEEQ and, if approved, FMX103. Our total selling, general and administrative expenses for the years ended December 31, 2019 and 2018 were approximately $45.1 million and $14.0 million, respectively.

Our ability to successfully commercialize AMZEEQ and, if approved, FMX103, is highly uncertain and depends on a number of factors, including market adoption of our product or product candidates by physicians and patients, market access uncertainty, our ability to scale to the market opportunity and the existence of existing and future products that may compete with ours. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary for successful commercialization of AMZEEQ or, if approved, FMX103.

Financial Income, net

Financial income, net, consists primarily of gains from interest earned from our bank deposits and financial income on our marketable securities offset by interest expenses on our long-term debt.

Taxes on Income

Effective January 1, 2018 the U.S. Tax cuts and Jobs Act (Tax Act) reduced the U.S Federal tax by 14% from 35% in 2017 to 21% in 2018, which remained the effective tax rate in 2019.

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately $224.4 million as of December 31, 2019. As of December 31, 2019 we incurred of net carry forward tax losses in the amount of $27.3 million in our U.S subsidiary Foamix Pharmaceuticals Inc.. As of December 31, 2019 we anticipated that we will be able to carry forward these tax losses to future tax years. Accordingly, we do not expect to pay taxes in the applicable jurisdiction until we have taxable income after the full utilization of our carry forward tax losses in that jurisdiction. We provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

During 2019 we incurred tax benefits of $0.2 million and during 2018 we incurred tax expenses of $ $0.2 million, related to our U.S. subsidiary.

Comparison of the Year Ended December 31, 2019 to the Year Ended December 31, 2018

Revenues

Our total revenues, consisting primarily of royalties, decreased by $3.2 million, or 89%, from $3.6 million in the year ended December 31, 2018 to $0.4 million in the year ended December 31, 2019, due to the ongoing suspension of the manufacturing of Finacea by LEO, following inadequate supply of quality-compliant batches of the API used in such product, as described above in “Item 1 – Business Development and License Agreements.”

Cost of revenues

There was no cost of revenues for the years ended December 31, 2018 and 2019, as revenues in both years consisted almost entirely of royalties, which do not bear related cost of revenue.

Research and development expenses

Our research and development expenses for the year ended December 31, 2019 were $51.2 million, representing a decrease of $13.3 million, or 21%, compared to $64.5 million for the year ended December 31, 2018. The decrease in research and development expenses resulted primarily from decrease of $21.4 million in clinical trial expenses due to the completion of AMZEEQ and FMX103 clinical trials, offset by an increase of $3.2 million in consulting expenses, an increase of $2.8 million in payroll and payroll-related expenses due to an increase in headcount and salaries and an increase of $2.6 million in payments related to the submission of our NDA for FMX103.

Selling, general and administrative expenses

Our general and administrative expenses for the year ended December 31, 2019 were $45.1 million, representing an increase of $31.1 million, or 222%, compared to $14.0 million for the year ended December 31, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of $18.0 million in connection with the pre-commercialization activities, an increase of $5.4 million in payroll and payroll-related expenses due to an increase in headcount as we built-out our sales and marketing organization in preparation of the AMZEEQ launch, a $3.1 million increase in costs relating to the Merger and a $2.0 million increase in other advisor and consulting expenses.

Operating loss

As a result of the foregoing, our operating loss for the year ended December 31, 2019, was $95.9 million, compared to an operating loss of $74.9 million for the year ended December 31, 2018, an increase of $21.0 million, or 28%.

Financial income, net

In the years ended December 31, 2019 and 2018, our financial income included mostly gains from marketable securities and interest earned on our bank deposits. In the year ended December 31, 2019, such income was offset by interest expenses on our long-term debt.

The financial income, net, by cash and non-cash components are as follows:

	Year ended December 31,	
	2019	2018
	(in thousands of U.S. dollars)	
Interest on bank deposits	$ 589	$ 297
Gain from marketable securities, net	1,083	688
Total income	1,672	985
Less:		
Interest and finance expenses on long-term debt	(921)	-
Other expenses	(19)	(17)
Foreign exchange loss, net	(213)	(27)
Total expenses	(1,153)	(44)
Financial income, net	$ 519	$ 941

Taxes on income

During 2019 and 2018, we did not generate taxable income in Israel and in our U.S. subsidiary, Foamix Pharmaceuticals Inc. For the year ended December 31, 2019 we incurred tax benefits relating to our U.S. subsidiary, in the amount of $0.2 million relating to an uncertain tax position. For the year ended December 31, 2018, we incurred tax expenses of $0.2 million.

Net Loss

Our net loss for the year ended December 31, 2019 was $95.2 million, compared to $74.2 million for the year ended December 31, 2018, an increase of $21.0 million, or 28%.

Liquidity

Since our inception, we have incurred losses from operations and negative cash flows from our operations. For the year ended December 31, 2019, we incurred a net loss of $95.2 million, which included $73.4 million used for operating activities. For the year ended December 31, 2018, we incurred a net loss of $74.2 million, which included $68.7 million used for operating activities.

As of December 31, 2019 and 2018, we had a working capital surplus of $47.1 million and $90.7 million, respectively, and an accumulated deficit of $310.6 million and $215.4 million, respectively.

Our principal source of liquidity as of December 31, 2019 consisted of cash and investments (including restricted cash and marketable securities) of $73.4 million and borrowings under our Credit Agreement of $35.0 million.

On July 29, 2019, we entered into a Credit Agreement with Foamix Pharmaceuticals Inc., or the Borrower, lenders from time to time party thereto, the subsidiary guarantors from time to time party thereto, or the Subsidiary Guarantors, Perceptive Credit Holdings II, LP, or Perceptive, as administrative agent, and OrbiMed Royalty & Credit Opportunities III, LP, or OrbiMed, that provides us with a senior secured delayed draw term loan facility in an aggregate principal amount of up to $50.0 million, or the Term Loan, for general corporate purposes.

In connection with the Merger, the Credit Agreement will be amended on or around the effective Date in order to add Menlo as a guarantor.

- The Term Loan is comprised of three tranches: (a) $15.0 million, which was available and drawn by the Borrower on July 29, 2019, the date of closing of the Credit Agreement, (b) $20.0 million, which was available until February 29, 2020 and drawn by the Borrower on December 17, 2019, following the FDA's approval of AMZEEQ, the listing of AMZEEQ in the FDA's "Orange Book," and our entrance into the Contract Manufacturing and Supply Agreement with ASM for the manufacture and supply of AMZEEQ, and (c) up to $15.0 million, which will become available to the Borrower subject to our achievement, prior to September 30, 2020, of certain revenue targets set forth in the Credit Agreement.

- The lenders are entitled to a fee in an amount equal to 1.0% of any principal amount actually drawn by the Borrower, upon such drawdown. Additionally, the outstanding principal amount accrues interest on a monthly basis (and is payable monthly in arrears) at an annual rate equal to the sum of 8.25% plus the greater of (i) the one-month $US LIBOR as of the second business day of each calendar month, and (ii) 2.75%. Upon the occurrence and during the continuance of any event of default, as defined in the Credit Agreement, the base interest of 8.25% shall automatically increase to 12.25% per annum.

- There will be no scheduled repayments of principal prior to July 29, 2023, the fourth anniversary of the closing date. Thereafter, the Borrower shall make monthly payments in an amount equal to 1.5% of the aggregate principal amount of the loans outstanding on such fourth anniversary date, and repay the entire remaining outstanding balance of the Term Loan on July 29, 2024, the final maturity date, subject to any acceleration as provided in the Credit Agreement, including upon an event of default. Also, a mandatory prepayment may be triggered by certain casualty losses or sales of the assets serving as collateral, as defined in the Credit Agreement.

- The Borrower has the right to optionally prepay all or any part of the outstanding principal amount of the Term Loan at any time, subject to payment of any accrued but unpaid interest on the principal being prepaid plus an additional prepayment premium equal to (i) 10.0% of any principal amount prepaid prior to the first anniversary of the closing date, (ii) 8.0% of any principal amount prepaid after the first anniversary and prior to the second anniversary of the closing date, (iii) 4.0% of any principal amount prepaid after the second anniversary and prior to the third anniversary of the closing date, and (iv) 2.0% of any principal amount prepaid after the third anniversary and prior to the fourth anniversary of the closing date.

- As additional consideration for the Term Loan, we issued to Perceptive and OrbiMed, upon closing of the Credit Agreement, a warrant to purchase a total of 1,100,000 of our ordinary shares at an exercise price of $2.09 per share – equal to the trailing five-day volume weighted average price of our ordinary shares on the trading day immediately prior to the closing date – and expiring on July 29, 2026.

In connection with our entry into the Credit Agreement described above, on July 29, 2019, we further entered into a Securities Purchase Agreement, or the Purchase Agreement, with Perceptive Life Sciences Master Fund Ltd., or Perceptive Life Sciences, an affiliate of Perceptive, pursuant to which we issued and sold to Perceptive Life Sciences, in a registered offering, an aggregate of 6,542,057 of our ordinary shares at a purchase price of $2.14 per share, representing the closing price of our ordinary shares on the last trading day prior to signing of the Purchase Agreement, for aggregate gross proceeds of approximately $14.0 million, before deducting offering expenses.

On August 19, 2019, we entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, as sales agent. Under the terms of the Sales Agreement, we may offer, issue and sell through Cantor, from time to time, ordinary shares having an aggregate offering price of up to $30.0 million. Under the Sales Agreement, Cantor may sell our ordinary shares by any method permitted by law and deemed to be an "at-the-market offering," as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on the Nasdaq, in each case pursuant to our effective registration statement on Form S-3 (File No. 333-224084) and the related base prospectus included in such registration statement, as supplemented by the prospectus supplement dated August 19, 2019. We have not made any sales under the Sales Agreement and on March 9, 2020, with the completion of the Merger, the Sales Agreement has been terminated.

We anticipate that with our existing cash and investments, along with Menlo's Cash and investment, funds that we may be entitled to receive upon reaching certain milestones under the Credit Agreement and our 2020 estimated income from AMZEEQ and FMX103, we will be able to fund our planned operating expenses and capital expenditure requirements into the second quarter of 2021. Prior to issuing this report, we revised our operating plan in order to reduce expenses and, until we are able to obtain further funding, we will only focus on (a) commercialization of AMZEEQ, (b) pre-commercialization and launch preparations for FMX103, assuming we receive regulatory approval, and (c) other general corporate expenses. We expect we will need additional funding to support our operating expenses and capital requirements during the second quarter of 2021 and beyond, including with regard to certain pipeline development activities, the commercialization of any of our product candidates if they are granted regulatory approval, and to fund our internal and external research and development efforts. 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.

Capital Resources

Overview

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

From inception through December 31, 2019, we have received net cash proceeds of approximately $328.1 million from the issuance of ordinary shares, preferred shares, debt, 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, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
Net cash (used in) / provided by:		(in thousands)	
Operating activities	$ (73,394)	$ (68,664)	$ (53,177)
Investing activities	41,869	(11,755)	37,755
Financing activities	$ 47,950	$ 92,374	$ 140

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 consists mainly of share-based compensation.

Net cash used in operating activities was $73.4 million in the year ended December 31, 2019, compared to $68.7 million in the year ended December 31, 2018. The increase of $4.7 million in the net cash used in operating activities in 2019 compared to 2018 was attributable primarily to the increase in company activity, mostly related pre-commercialization efforts in order to support the commercialization of AMZEEQ and applying for FDA approval for FMX103, offset by a reduction in activities relating to clinical trials following the completion of the Phase III clinical trials of AMZEEQ and FMX103 in the course of 2018.

Net cash used in investing activities

Net cash provided by investing activities was primarily related to proceeds from the sale and maturity of marketable securities, offset by investment in bank deposits and marketable securities. Net cash provided by investing activities was $41.9 million in the year ended December 31, 2019, compared to $11.8 million used in in the year ended December 31, 2018. The change of $53.7 million in the year ended December 31, 2019 compared to the year ended December 31, 2018 was attributable primarily to increase proceeds from sale and maturity of marketable securities and bank deposits.

Net cash provided by financing activities

Net cash provided by financing activities was $47.9 million in the year ended December 31, 2019, compared to $92.4 million in the year ended December 31, 2018. The decrease of $44.5 in net cash provided by financing activities in the year ended December 31, 2019 compared to the year ended December 31, 2018 was attributable primarily to the reduction in the scope of our share offerings in 2019, after conducting two offerings in 2018 in which we received aggregate net proceeds of approximately $16.1 million from issuance of shares to OrbiMed and of approximately $75.4 million from issuance of shares in the follow-on offering which closed on September 18, 2018, our financing in 2019, included the first two tranches of the Term Loan withdrawn under the Credit Agreement and the proceeds from the share offering to Perceptive Life Sciences under the Purchase Agreement.

Cash and funding sources

The table below summarizes our main sources of financing for the years ended December 31, 2019, 2018 and 2017:

	Proceeds from our underwritten public offerings[1]	Proceeds from our direct public offerings	Proceeds from loans and issuance of warrant (1)	Proceeds from issuance of ordinary shares	Payments from licensees	Total
			(in thousands of U.S. dollars)			
2019	$ -	$ 13,714	$ 33,903	$ 333	$ 1,374	$ 49,324

2018	$ 75,356	$ 16,131	$ -	$ 887	$ 3,457	$ 95,831
2017	$ -	$ -	$ -	$ 161	$ 5,978	$ 6,139

(1) Net of issuance costs.

Our sources of financing in the year ended December 31, 2019 totaled $49.6 million and consisted primarily of $33.9 million of net proceeds from the first two tranches of the Term Loan, $13.7 million of net proceeds from the registered offering under the Purchase Agreement and $1.4 million of payments from licensees.

Our sources of financing in the year ended December 31, 2018 totaled $95.8 million and consisted primarily of $75.4 million of net proceeds from our underwritten follow-on offering which closed in September 2018 and $16.1 million of net proceeds from our registered direct offering to OrbiMed.

Other than our commitments under the Credit Agreement, we currently have no ongoing material financial commitments, such as lines of credit, that may affect our liquidity over the next five years.

Contractual Obligations

Our significant non-cancelable contractual obligations as of December 31, 2019 are summarized in the following table:

	Payments due by period					
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years	Other
	(in thousands of U.S. dollars)					
Operating lease obligations[1]	$ 1,849	$ 1,164	$ 685	$ -	$ -	$ -
Credit Agreement[2]	52,503	3,914	14,787	33,802	-	-
Liability for employee severance benefits[3]	433	-	-	-	-	433
Purchase Obligation [4]	4,799	4,799	-	-	-	-
Total	$ 59,584	$ 9,877	$ 15,472	$ 33,802	$ -	$ 433

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(1) Operating lease obligations consist of lease of our facilities and lease of vehicles.

(2) On July 29, 2019 we secured up to $50 million in debt which matures on July 29, 2024 and bears interest of 8.25% plus the greater of the one-month LIBOR and 2.75%. Refer to Note 10 to our consolidated financial statements included elsewhere in this report for further information.

(3) The liability is considered long term, however we cannot estimate the exact period in which they will be paid.

(4) Purchase obligations primarily include non-cancelable commitments under our contract manufacturing agreements.

Funding requirements

We anticipate that with our existing cash and investments, along with Menlo's Cash and investment, funds that we may be entitled to receive upon reaching certain milestones under the Credit Agreement and our 2020 estimated income from AMZEEQ and FMX103, we will be able to fund our planned operating expenses and capital expenditure requirements into the second quarter of 2021. Prior to issuing this report, we revised our operating plan in order to reduce expenses and, until we are able to obtain further funding, we will only focus on (a) commercialization of AMZEEQ, (b) pre-commercialization and launch preparations for FMX103, assuming we receive regulatory approval, and (c) other general corporate expenses. We expect we will need additional funding to support our operating expenses and capital requirements during the second quarter of 2021 and beyond, including with regard to certain pipeline development activities, the commercialization of any of our product candidates if they are granted regulatory approval, and to fund our internal and external research and development efforts.

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, inter alia:

- selling, marketing and patent-related activities undertaken in connection with the commercialization of AMZEEQ, and, if approved, FMX103 and any other product candidates, as well as costs involved in the development of an effective sales and marketing organization;
- the progress, timing and completion of preclinical testing and clinical trials for future pipeline product candidates;
- the time and costs involved in obtaining regulatory approval for FMX103 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 efforts necessary to institute post-approval regulatory compliance requirements for AMZEEQ;
- the number of potential new products we identify and decide to develop;
- the costs involved in filing and prosecuting patent applications, defending third party observations and pre-grant oppositions and obtaining, maintaining and enforcing patents or defending against review, 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 our drug product AMZEEQ, our product candidate FMX103 and any other pipeline product that is commercialized.

Our operating plan may change as a result of many factors currently unknown to us, and any such change may affect our funding requirements. We have never before launched a product commercially, and the costs involved in such commercial launch may exceed our expectations. We may therefore 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.

Our capital expenditures for 2019 and 2018 amounted to $1.1 million and $0.6 million, respectively. During 2019, these expenditures were primarily related to laboratory equipment, computers and leasehold improvements.

For more information as to the risks associated with our future funding needs, see “Item 1A - Risk Factors—Risks Related to Our Business and Industry—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” included herein.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are more fully described in Note 2, “Significant Accounting Policies,” to the consolidated financial statements included in “Financial Statements and Supplementary Data” of this Annual Report, we believe that the following accounting policies are the most critical to assist shareholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operations. These policies relates to the more significant areas involving management’s judgments and estimates and requires our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of the matters that are inherently uncertain.

Clinical trial accruals

Clinical trial costs are charged to research and development expense as incurred. We accrue for expenses resulting from obligations under contracts with CROs. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. Our objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments will be recorded as other assets, which will be recognized as expenses as services are rendered. The CRO contracts generally include pass-through fees including, but not limited to, regulatory expenses, investigator fees, travel costs and other miscellaneous costs. We estimate our clinical accruals based on reports from and discussion with clinical personnel and the CRO as to the progress or state of completion of the trials. We estimate accrued expenses as of each balance sheet date in the consolidated financial statements based on the facts and circumstances known at that time. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the CROs.

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2, “Significant Accounting Policies,” to the consolidated financial statements included in “Financial Statements and Supplementary Data” of this Annual Report.

ITEM 7A - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a “smaller reporting company,” as defined by Item 10 of Regulation S-K, we are not required to provide quantitative or qualitative disclosures about market risk.

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2019

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of

FOAMIX PHARMACEUTICALS LTD.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Foamix Pharmaceuticals Ltd. and its subsidiary (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2(y) to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

Tel-Aviv, Israel
March 12, 2020

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2006.

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31	
	2019	2018
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 43,759	$ 27,868
Restricted cash	825	250
Short term bank deposits	12,102	24,047
Investment in marketable securities (Note 4)	16,246	46,669
Restricted investment in marketable securities (Note 4)	434	268
Trade receivable	135	1,066
Other (Note 13a)	1,557	999
Inventory (Note 5)	1,356	-
TOTAL CURRENT ASSETS	76,414	101,167
NON-CURRENT ASSETS:		
Investment in marketable securities (Note 4)	-	150
Restricted investment in marketable securities (Note 4)	-	133
Property and equipment, net (Note 6)	2,885	2,235
Operating lease right of use assets (Note 7)	1,694	-
Other	166	46
TOTAL NON-CURRENT ASSETS	4,745	2,564
TOTAL ASSETS	$ 81,159	$ 103,731

The accompanying notes are an integral part of these consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31	
	2019	**2018**
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Trade payables	$ 19,352	$ 6,327
Accrued expenses	3,381	351
Employee related obligations	5,231	3,498
Operating lease liabilities (Note 7)	1,092	-
Other	270	292
TOTAL CURRENT LIABILITIES	29,326	10,468
LONG-TERM LIABILITIES:		
Liability for employee severance benefits (Note 8)	424	367
Operating lease liabilities (Note 7)	653	-
Long-term debt (Note 10)	32,725	-
Other liabilities	456	714
TOTAL LONG-TERM LIABILITIES	34,258	1,081
TOTAL LIABILITIES	63,584	11,549
COMMITMENTS AND CONTINGENCIES (Note 9)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 135,000,000 and 90,000,000 Ordinary Shares as of December 31, 2019 and December 31, 2018; issued and outstanding: 61,580,544 and 54,351,140 Ordinary Shares as of December 31, 2019 and December 31, 2018, respectively	2,659	2,331
Additional paid-in capital	325,498	305,303
Accumulated deficit	(310,587)	(215,409)
Accumulated other comprehensive income (loss)	5	(43)
TOTAL SHAREHOLDERS' EQUITY	17,575	92,182
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 81,159	$ 103,731

The accompanying notes are an integral part of these consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Year ended December 31		
	2019	**2018**	**2017**
REVENUES (Note 13b)	$ 443	$ 3,595	$ 3,669
COST OF REVENUES	-	-	13
GROSS PROFIT	443	3,595	3,656
OPERATING EXPENSES:			
Research and development	51,202	64,474	57,779
Selling, general and administrative	45,114	14,013	11,491
TOTAL OPERATING EXPENSES	96,316	78,487	69,270
OPERATING LOSS	95,873	74,892	65,614
FINANCE INCOME (Note 13c)	(1,672)	(985)	(1,134)
FINANCE EXPENSES (Note 13c)	1,153	44	71
LOSS BEFORE INCOME TAX	95,354	73,951	64,551
INCOME TAX (Note 12)	(176)	212	1,164
NET LOSS FOR THE YEAR	$ 95,178	$ 74,163	$ 65,715
LOSS PER SHARE BASIC AND DILUTED	$ 1.66	$ 1.70	$ 1.76
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	57,292	43,660	37,376

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		
	2019	**2018**	**2017**
NET LOSS	$ 95,178	$ 74,163	$ 65,715
OTHER COMPREHENSIVE INCOME:			
Net unrealized losses (gains) from marketable securities	(47)	(59)	5
Gains (losses) on marketable securities reclassified into net loss	2	(5)	-
Net unrealized losses (gains) on derivative financial instruments	(3)	74	(146)
Gains (losses) on derivative financial instruments reclassified into net loss	-	(60)	137
TOTAL OTHER COMPREHENSIVE INCOME	(48)	(50)	(4)
TOTAL COMPREHENSIVE LOSS	$ 95,130	$ 74,113	$ 65,711

The accompanying notes are an integral part of these consolidated 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 income (loss)	Total
	Number of shares	Amounts	Amounts			
BALANCE AT JANUARY 1, 2017	**37,167,791**	**$ 1,561**	**$ 204,052**	**$ (75,566)**	**$ (62)**	**$ 129,985**
CHANGES DURING 2017:						
Comprehensive income (loss)	-	-	-	(65,715)	4	(65,711)
Exercise of warrants (Note 11b)	191,793	8	(8)	-	-	-
Exercise of options and restricted share units (Note 11e)	138,544	7	154	-	-	161
Share-based compensation (Note 11e)	-	-	4,166	-	-	4,166
BALANCE AT DECEMBER 31, 2017, as previously reported	**37,498,128**	**$ 1,576**	**$ 208,364**	**$ (141,281)**	**$ (58)**	**$ 68,601**
Impact of initial adoption of new accounting standards (Note 4)	-	-	-	35	(35)	-
CHANGES DURING 2018:						
Comprehensive income (loss)	-	-	-	(74,163)	50	(74,113)
Issuance of Ordinary Shares through a public offering, net of $5.2 issuance costs (note 11c)	13,420,500	599	74,757	-	-	75,356
Issuance of Ordinary Shares through a securities purchase agreement, net of $39 issuance costs (note 11d)	2,940,000	134	15,997	-	-	16,131
Exercise of warrants (Note 11b)	178,468	8	832	-	-	840
Exercise of options and restricted share units (Note 11e)	314,044	14	33	-	-	47
Share-based compensation (Note 11e)	-	-	5,320	-	-	5,320
BALANCE AT DECEMBER 31, 2018	**54,351,140**	**$ 2,331**	**$ 305,303**	**$ (215,409)**	**$ (43)**	**$ 92,182**
CHANGES DURING 2019:						
Comprehensive income (loss)	-	-	-	(95,178)	48	(95,130)
Issuance of Ordinary Shares and warrants, net of $359 issuance costs (Notes 10 and 11)	6,542,057	297	14,714	-	-	15,011
Exercise of options, restricted share units and shares issued under employee share purchase plan (Note 11e)	687,347	31	586	-	-	617
Share-based compensation (Note 11e)	-	-	4,895	-	-	4,895
BALANCE AT DECEMBER 31, 2019	**61,580,544**	**$ 2,659**	**$ 325,498**	**$ (310,587)**	**$ 5**	**$ 17,575**

The accompanying notes are an integral part of these consolidated financial statements

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31		
	2019	**2018**	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net Loss	$ (95,178)	$ (74,163)	$ (65,715)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	350	319	221
Loss from sale and disposal of fixed assets	18	44	134
Changes in marketable securities and bank deposits, net	(357)	201	97
Changes in accrued liability for employee severance benefits, net of retirement fund profit	57	(70)	57
Share-based compensation	4,895	5,320	4,166
Non-cash finance expenses (income), net	140	43	(47)
Changes in operating asset and liabilities:			
Decrease (increase) in trade and other receivables	373	(308)	1,915
Decrease (increase) in other non-current assets	(131)	(14)	4
Increase in accounts payable and accruals	18,053	238	5,003
Increase in inventory	(1,356)	-	-
Increase (decrease) in other liabilities	(258)	(274)	988
Net cash used in operating activities	(73,394)	(68,664)	(53,177)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(1,058)	(567)	(1,518)
Proceeds from sale of fixed assets	40	10	33
Investment in bank deposits	(26,013)	(39,000)	(17,000)
Investment in marketable securities	(18,951)	(38,652)	(22,839)
Proceeds from sale and maturity of marketable securities and bank deposits	87,851	66,454	79,079
Net cash provided by (used in) investing activities	41,869	(11,755)	37,755
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of warrants	-	840	-
Proceeds from exercise of options and issuance of shares under the employee shares purchase plan	365	47	161
Withholding tax from net exercise of restricted share units	(32)	-	-
Proceeds from issuance of Ordinary Shares, net of issuance costs	13,714	16,131	
Proceeds from issuance of Ordinary Shares through a public offering, net of $5.2 issuance costs	-	75,356	-
Proceeds from debt financing and issuance of warrants, net of $1,097 issuance costs	33,903	-	-
Payments in respect of bank borrowings	-	-	(21)
Net cash provided by financing activities	47,950	92,374	140
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	16,425	11,955	(15,282)
EFFECT OF EXCHANGE RATE ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	41	(43)	48
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE YEAR	28,118	16,206	31,440
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	$ 44,584	$ 28,118	$ 16,206
Cash and cash equivalents	43,759	27,868	15,956
Restricted cash	825	250	250
TOTAL CASH, CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	$ 44,584	$ 28,118	$ 16,206

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31		
	2019	**2018**	**2017**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Cashless exercise of warrants and restricted share units	11	11	11
Issuance of shares under employee share purchase plan	284	-	-
Property and equipment purchases included in accounts payable and accruals	-	-	1
Additions to operating lease right of use assets and liabilities	1,175	-	-
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for taxes	-	587	478
Interest received	1,359	1,173	1,209
Interest paid	802	-	*-

* Represents an amount less than $1.

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 - NATURE OF OPERATIONS

Foamix Pharmaceuticals Ltd. (hereinafter “Foamix”) is an Israeli company incorporated in 2003.

Foamix’s shares were publicly traded on the Nasdaq Global Market under the symbol “FOMX” from its initial public offering in September 2014 until March 9, 2020.

Foamix is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies in dermatology. On October 18, 2019, the U.S. Food and Drug Administration (“FDA”) approved Foamix’s first drug product, AMZEEQ (minocycline) topical foam, 4%, formerly known as FMX101, a once-daily topical antibiotic for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. AMZEEQ was launched and has been available for prescribing since January 13, 2020.

Foamix is also developing a product candidate, FMX103 (minocycline) topical foam, 1.5%, for the treatment of moderate-to-severe papulopustular rosacea in adults. Both AMZEEQ and FMX103 were developed using Molecule Stabilizing Technology, a proprietary foam platform designed to optimize the topical delivery of minocycline, an active pharmaceutical ingredient, that was available only in oral form until the FDA’s approval of AMZEEQ.

Foamix also licensed certain 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. (hereinafter referred to as the "Subsidiary"). The Subsidiary was incorporated to assist Foamix with regard to commercialization activities, regulatory affairs and business development relating to its pipeline and technology.

On November 10, 2019, Foamix entered into an Agreement and Plan of Merger (the "Merger Agreement") with Menlo Therapeutics, Inc. ("Menlo") and Giants Merger Subsidiary Ltd. (“Merger Sub”), a direct and wholly-owned subsidiary of Menlo. Under the terms of the agreement, Merger Sub agreed to merge with and into Foamix, with Foamix continuing as the surviving corporation and a wholly-owned subsidiary of Menlo (the “Merger”). On March 9, 2020, the Merger was completed and Foamix is now a wholly-owned subsidiary of Menlo, the legal acquirer. Foamix will cease to be a reporting company as of March 19, 2020 and all future filings of the combined company will be made by Menlo. As of the issuance of the financial statements, Foamix incurred transaction expenses in the amount of approximately $5.8 million.

At the effective time of the Merger (the “Effective Time”), each Foamix Ordinary Share, par value NIS 0.16 per share, issued and outstanding immediately prior to the Effective Time was exchanged for (i) 0.5924 shares (the “Exchange Ratio”) of common stock of Menlo and (ii) one contingent stock right (a “CSR”, and collectively, the “CSRs”). The CSRs are governed by the Contingent Stock Rights Agreement (the “CSR Agreement”), dated as of March 9, 2020, by and between Menlo and American Stock Transfer & Trust Company, LLC, and represent the non-transferable contractual right to receive shares of common stock of Menlo if specified events occur within agreed time periods. Pursuant to the CSR Agreement, each CSR may become convertible on May 31, 2020 or upon the occurrence of specified events relating to Menlo’s Phase III PN Trials, and, if so converted, will entitle its holder to receive from Menlo additional shares of Menlo common stock.

The Merger will be accounted in accordance with Accounting Standards Codification Topic 805, “Business Combinations,” using the acquisition method of accounting with Foamix as the accounting acquirer. Since Menlo, as the parent company of Foamix after the Merger, is the legal acquirer, the Merger will be accounted for as a reverse acquisition.

NOTE 1 - NATURE OF OPERATIONS (continued):

Since incorporation through December 31, 2019, Foamix and its subsidiary (hereinafter referred to as "the Company") incurred losses and negative cash flows from operations mainly attributable to its development efforts and has an accumulated deficit of $310,587. The Company has financed its operations mainly through the issuance of shares through private and public financing rounds, debt financing, warrants and payments received pursuant to the terms of development and licensing agreements. As mentioned above, on March 9, 2020, the Merger with Menlo was completed. As of the issuance date of these financial statements, the Company's cash and investments, along with Menlo's cash and investments, funds the Company may be entitled to receive upon reaching certain milestones under its credit agreement (see note 10) and the Company's 2020 estimated income from AMZEEQ and FMX103, provide sufficient resources to fund its operations through at least the next 12 months. Prior to issuing these financial statements, the Company revised its operating plan in order to reduce expenses and, until it is able to obtain further funding, will only focus on (a) commercialization of AMZEEQ, (b) pre-commercialization and launch preparations for FMX103, assuming it receives regulatory approval, and (c) other general corporate expenses. In order to develop and commercialize any future product candidates if they are granted regulatory approval, the Company and Menlo (the "Combined Company") may be required to obtain further funding through public or private offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to the Combined Company on acceptable terms, or at all. If the Combined Company is unable to raise capital when needed or on attractive terms, it may be forced to delay, reduce or eliminate its research and development programs or commercialization and manufacturing efforts.

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 clinical trial accruals.

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 including profits from intercompany sales not yet realized outside the Company, have been eliminated upon consolidation.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 at balance sheet date are less than one year are included in short-term deposits. The interest rates on the Company's deposits range between 2.23%-3.15%. 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

Marketable debt securities:

Marketable debt securities are classified as available for sale and are recorded at fair value. Management determines the appropriate classification of its investments in securities at the time of purchase. Classifications of debt securities in the balance sheet are determined based on the maturity date of the securities.

Dividend and interest income, including amortization of the premium and discount arising at acquisition, as well as realized gains and losses, are included in financial income.

Unrealized gains, 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 are included in financial income, net.

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.

Marketable equity securities:

The Company's marketable equity securities are recorded at fair market value and, beginning January 1, 2018, following the adoption of ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10), unrealized gains and losses are included in other income (expense), net in the consolidated statements of operations. Prior to January 1, 2018, unrealized gains, net of taxes, were reflected in other comprehensive income (loss) and unrealized losses were reflected in other comprehensive income (loss).

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

h. Derivatives and Hedging

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. Inventory

Prior to the date the Company obtains regulatory approval for its product candidates, inventory costs related to commercial production are expensed as research and development expense. Once regulatory approval is obtained, the Company capitalizes such costs as inventory. Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out ("FIFO") method. The Company periodically reviews its inventory levels and writes down inventory that is expected to expire prior to being sold, inventory in excess of expected sales requirements and inventory that fails to meet commercial sale specifications, with a corresponding charge to cost of goods sold.

j. 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
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.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

k. 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, 2019, the Company did not recognize an impairment loss for its long-lived assets.

l. 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 three years ended December 31, 2019.

m. Debt

Debt discounts created as a result of the allocation of proceeds received from a debt issuance to warrants issued are amortized to interest expense under the effective interest method over the life of the recognized debt liability.

Debt issuance costs include the costs of debt financings undertaken by the Company, including legal fees and other direct costs of the financing. Debt issuance costs related to a recognized debt liability are presented on the consolidated balance sheet as a direct deduction from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt, using the effective interest method.

n. Leases

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires lessees to record assets and liabilities on the balance sheet for all leases. The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company recognizes the lease payments in the consolidated statements of operations on a straight-line basis over the lease period.

The Company adopted the standard as of January 1, 2019 on a modified retrospective basis and did not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carryforward the historical lease classification and not separate lease and non-lease components for the leases.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. 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.

p. 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 using the straight-line method. Forfeitures are recognized as they occur.

Share-based payments related to the employee share purchase plan ("ESPP") are recognized based on the fair value of each award estimated on the first day of the offering period and recognized as an expense over the offering period using the straight-line method.

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.

Prior to December 31, 2018, when options and restricted share units (hereinafter "RSUs") were granted as consideration for services provided by nonemployees, the grants were 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 was measured on a final basis at the end of the related service period and was recognized over the related service period using the straight-line method.

On January 1, 2019 the Company adopted the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, nonemployee share-based transactions are being measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions.

NOTE 2−SIGNIFICANT ACCOUNTING POLICIES (continued):

q. Revenue recognition

On January 1, 2018 the Company adopted ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). According to the standard, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied.

An entity only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer, after considering any price concession expected to be provided to the customer, when applicable. At contract inception, the entity assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The entity then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The adoption of the new standards did not change the Company’s revenue recognition as the majority of the Company’s revenues in the year ended December 31, 2019 and 2018, were driven from royalties from license agreements for products, developed combining the Company's foam technology with a drug selected by the licensee. The Company does not have future performance obligations under the license arrangements. The revenues are recorded based on the sales that occurred during the relevant period provided by licensees.

Prior to January 1, 2018 and before the adoption of the new standard, the Company's revenues also included development services driven from the development and license agreements. Revenue recognition from those agreements were recognized as follows:

The significant deliverables in the agreements between the Company and its licensees were the obligation of Company to provide development services and the grant of an exclusive license to the specific product developed. These deliverables were combined into one single unit of accounting for revenue recognition purposes since: (i) each element did not have value on a stand-alone basis; (ii) in order to develop the combined formulation in the licensed product, the use of the Company’s propriety technology was required. Therefore, the Company was 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: (i) development payments, including upfront payments, cost reimbursements and payments contingent only upon passage of time (together, - “Development Service Payments”); (ii) payments contingent solely upon performance or achievement of clinical results by the Company’s licensees (“Contingent Payments”); (iii) royalties calculated as a percentage of sales of the developed the products made by the Company's licensees.

Revenues from Development Service Payments under development and license agreements were recognized as the services were provided. When the Company received a portion of the Development Service Payment before performance of such services, these advances were recorded as deferred revenues and recognized as revenues as services were performed. Contingent Payments were recognized when the licensee’s performance or achievement event occurred, and royalties were recognized when subsequent sales were made by the licensees.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 2−SIGNIFICANT ACCOUNTING POLICIES (continued):

r. Research and development costs

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of clinical trials, clinical trial supplies, 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.

s. Clinical trial accruals

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

t. 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.

u. 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 Ordinary Shares outstanding during the year. Diluted net loss per share is based upon the weighted average number of Ordinary Shares and of Ordinary Shares equivalents outstanding when dilutive. Ordinary Share equivalents include outstanding share based payment arrangements and warrants which are included under the treasury share method when dilutive.

The following average share options, RSUs, warrants and incremental share to be issued under the ESPP were excluded from the calculation of diluted net loss per Ordinary Share because their effect would have been anti-dilutive for the year presented (share data):

	Year ended December 31		
	2019	**2018**	**2017**
Outstanding share options, RSUs and shares under ESPP	6,115,124	4,684,916	3,657,612
Warrants	467,123	508,154	1,498,718

NOTE 2−SIGNIFICANT ACCOUNTING POLICIES (continued):

v. 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.

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.

w. 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.

x. Comprehensive loss

Comprehensive loss includes, in addition to net loss, unrealized holding gains and losses on available-for-sale debt securities and derivative instruments designated as cash flow hedge (net of related taxes where applicable). For the year ended December 31, 2017, the comprehensive loss included also available-for-sale equity securities.

Reclassification adjustments for gain or loss of available for sales securities are included in finance expenses net in the statement of operations.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

y. Newly issued and recently adopted accounting pronouncements:

Accounting pronouncements adopted in period:

1) In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires lessees to record assets and liabilities on the balance sheet for all leases. The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

   The adoption of the standard resulted in recognition of $1,357 of lease assets and lease liabilities as of January 1, 2019 on the Company's consolidated balance sheets. The weighted-average interest rate used to discount future lease payments was 4.8%.

2) On January 1, 2019 the Company adopted the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, nonemployee share-based transactions are being measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions. The adoption of this slandered had no material impact on the Company's consolidated financial statements.

3) In August 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-12, Derivatives and Hedging (Topic 815), Targeted Improvements to Accounting for Hedging Activities. Among other things, the guidance eliminated the requirement to separately measure and report hedge ineffectiveness and generally requires the entire change in the fair value of a hedging instrument to be presented in the same income statement line as the hedged item. As ASU 2017-12 was effective for fiscal years beginning after December 15, 2018, the Company adopted the ASU on January 1, 2019 with no 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, 2019, and December 31, 2018, are classified in the tables below in one of the three categories described in note 2v above:

	December 31, 2019		
	Level 1	**Level 2**	**Total**
Marketable securities	$ 1,020	$ 15,660	$ 16,680

	December 31, 2018		
	Level 1	**Level 2**	**Total**
Marketable securities	$ 991	$ 46,229	$ 47,220
Currency options designated as hedging instruments (current liability)	-	$ (3)	$ (3)

The Company's 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.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 3 - FAIR VALUE MEASUREMENTS (continued):

Foreign exchange risk management

Occasionally, the Company purchases and writes non-functional currency options in order to hedge the currency exposure on the Company's cash flow. The currency hedged items are denominated in New Israeli Shekels ("NIS"). The purchasing and writing of options is part of a comprehensive currency hedging strategy with respect to salary and rent expenses denominated in NIS. These transactions are at zero cost for periods of up to one year. The counterparties to the derivatives are major banks in Israel. As of December 31, 2019, there were no hedged amounts.

As of December 31, 2019 and 2018, the Company has a lien in the amount of $290 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, 2019, and December 31, 2018 consist mainly of debt and mutual funds securities. The debt 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.

As of January 1, 2018, following the adoption of ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10), equity securities with readily determinable fair value are measured at fair value. The changes in the fair value of equity investments are recognized through net income. Adoption of the standard was applied through a cumulative one-time adjustment of $35 to the accumulated deficit.

The following table sets forth the Company's marketable securities:

	December 31	
	2019	2018
Israeli mutual funds	$ 1,020	$ 991
Certificates of deposit	151	2,773
U.S Government and agency bonds	6,031	25,215
U.S Treasury bills	9,478	18,241
Total	$ 16,680	$ 47,220

At December 31, 2019 and 2018, the fair value, cost and gross unrealized holding gains and losses of the marketable securities owned by the Company were as follows:

	December 31, 2019			
	Fair value	Cost or Amortized cost	Gross unrealized holding loss	Gross unrealized holding gains
Certificates of deposit	$ 151	$ 151	$ -	$ -
U.S Government and agency bonds	6,031	6,030	-	1
U.S Treasury bills	9,478	9,475	-	3
Total	$ 15,660	$ 15,656	$ -	$ 4

(U.S. dollars in thousands, except share and per share amounts)

NOTE 4 - MARKETABLE SECURITIES (continued):

	December 31, 2018			
	Fair value	Cost or Amortized cost	Gross unrealized holding loss	Gross unrealized holding gains
Israeli mutual funds	$ 2,773	$ 2,790	$ 17	$ -
Certificates of deposit	25,215	25,236	22	1
U.S. Government and agency bonds	18,241	18,243	3	1
Total	$ 46,229	$ 46,269	$ 42	$ 2

As of December 31, 2018, 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, 2018.

As of December 31, 2019, and 2018, the Company's debt securities had the following maturity dates:

	Market value December 31	
	2019	2018
Due within one year	$ 15,660	$ 46,079
1 to 2 years	-	150
Total	$ 15,660	$ 46,229

During the years ended December 31, 2019 and 2018, the Company received proceeds of $49,819 and $32,247, respectively upon the sale and maturity of marketable securities.

$434 and $401 of the Company's marketable securities were restricted as of December 31, 2019, and 2018, 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.

NOTE 5 – INVENTORY

Inventories are stated at the lower of cost and net realizable value with cost determined on a first-in, first-out basis by product. The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. The Company commenced capitalizing inventory for AMZEEQ upon FDA approval of AMZEEQ on October 18, 2019. No inventory was capitalized prior to October 18, 2019.

As of December 31, 2019, the Company's inventory includes finished goods in the amount of $856, raw materials in the amount of $500 and no inventory write-down was recorded.

NOTE 6 - PROPERTY AND EQUIPMENT

	December 31	
	2019	2018
Cost:		
Leasehold improvements	$ 1,052	$ 978
Computers and software	646	515
Laboratory equipment	2,028	1,399
Furniture	391	245
Vehicles	-	82
	4,117	3,219
Less:		
Accumulated depreciation and amortization	1,232	984
Property and Equipment, net	$ 2,885	$ 2,235

(U.S. dollars in thousands, except share and per share amounts)

NOTE 6 - PROPERTY AND EQUIPMENT (continued):

Depreciation and amortization expense totaled $350, $319 and $221 for the years ended December 31, 2019, 2018 and 2017, respectively.

During the years ended December 31, 2019, 2018 and 2017, the Company disposed of fixed assets in the net amount of $16, $42 and $104, respectively. Losses from sales of fixed assets for the years ended December 31, 2019, 2018 and 2017 were $2, $2 and $30, respectively.

NOTE 7 – OPERATING LEASE

The Company leases research and development facilities in Israel and executive offices in the United States under several lease agreements. The lease agreement for the facilities in Israel is linked to the Israeli consumer price index (“CPI”) and due to expire in December 2020.

On March 13, 2019, the Subsidiary signed an amendment to the original lease agreement for its facilities in the U.S. (“The Amendment”). The Amendment includes an extension of the lease period of the 10,000 square feet previously leased under the original agreement (the "Original Space") and an addition of 4,639 square feet (the "Additional Space”). The Subsidiary entered the Additional Space following a period of preparation by the lessor completed during September 2019 (the "Commencement Date"). The Amendment is due to expire on August 31, 2022.

Pursuant to The Amendment of the lease on the Current Space, the Company recognized an additional right of use asset and liability in the amount of $713. The Additional Space was considered a new lease agreement and was recognized as a right of use asset and liability, in the amount of $302, on the Commencement Date.

In July 2017, the Company entered into operating lease agreements in connection with the leasing of several vehicles. The lease periods are generally for three years and the payments are linked to the Israeli CPI. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing company, representing approximately three months of lease payments. These amounts have been recorded as part of the operating lease right to use assets.

Operating lease costs for the year ended December 31, 2019 are as follows:

	Year Ended December 31 2019
Office lease expenses	$ 794
Vehicles lease expenses	$ 95

The operating lease costs include variable lease payments of $45.

Operating cash flows, for amounts included in the measurement of lease liabilities are as follows:

	Year Ended December 31 2019
Office lease expenses	$ 839
Vehicles lease expenses	$ 156

(U.S. dollars in thousands, except share and per share amounts)

NOTE 7 – OPERATING LEASE (continued):

Supplemental information related to leases are as follows:

	December 31 2019
Operating lease right-of-use assets	$ 1,694
Operating lease liabilities	$ 1,745
Weighted average remaining lease term	1.93
Weighted average discount rate	6.08%

Maturities of lease liabilities are as follows:

2020	$ 1,164
2021	455
2022	230
Total lease payments	1,849
Less imputed interest	(104)
Total lease liability	$ 1,745

As of December 31, 2019, the Company had a lien in the amount of $144 on the Company's marketable securities in respect of bank guarantees granted in order to secure the lease agreements.

Leases prior to the adoption of the new standard:

Operating lease expenses for the years ended December 31, 2018 and December 31, 2017 were $872 and $667 respectively.

Future minimum lease commitments under non-cancelable operating lease agreements according to ASC840, as of December 31, 2018 were as follows:

2019	$ 746
2020	682
2021 and thereafter	21
Total	$ 1,449

NOTE 8 - 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, 2019 and 2018, represents the Company's obligation that has not been secured by deposits to employee severance funds.

The amount of severance payment expenses to Israel employees were $719, $592 and $569 for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, respectively.

Beginning September 2017, the Company has retirement savings plans available to all employees of the Subsidiary, which are intended to qualify as deferred compensation plans under Section 401(k) of the Internal Revenue Code (the "401(k) Plans"). The Company made contributions to these 401(k) Plans during the years ended December 31, 2019, 2018 and 2017 of approximately $203, $84 and $35, respectively.

During 2020, the Company expects to deposit approximately $1,014 with respect to employee's severance benefits.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Litigation and contingencies

Seven lawsuits have been filed in the U.S. against the Company in connection with the Merger. The lawsuits generally allege that the registration statement on Form S-4 and the prospectus/joint proxy statement included therein included false or misleading information regarding the Merger in violations of Section 14(a) and Section 20(a) of the Exchange Act and/or Rule 14a 9 promulgated under the Exchange Act. In addition, one of the lawsuits alleges that the members of the Company's board of directors breached their fiduciary duties in connection with the Merger. The plaintiffs are seeking, among other things, to enjoin consummation of the Merger, or alternatively rescission or rescissory damages; to compel the individual defendants to disseminate a joint proxy statement/prospectus that does not contain any untrue statements of material fact and that states all material facts required in it or necessary to make the statements contained therein not misleading; a declaration that defendants violated Sections 14(a) and/or 20(a) of the Exchange Act; a declaration that the Merger Agreement was entered into in breach of fiduciary duty and is therefore invalid and unenforceable; an order directing the individual defendants to commence a sale process for the Company and obtain a transaction; and an award of costs, including attorneys' and experts' fees and expenses, as well as an accounting of damages allegedly suffered by the plaintiffs. The Company believes the lawsuits are without merit and intend to defend vigorously against all claims asserted and it is management's view that the financial statements include an adequate provision in respect of the claims.

NOTE 10 - LONG-TERM DEBT

On July 29, 2019 (the “Closing Date”) the Company secured up to $50 million in debt from two of its current shareholders, who are considered related parties (the “lenders”) and entered into a Securities Purchase Agreement with one of the lenders for gross proceeds of approximately $14 million, before deducting offering expenses (see Note 11).

The debt consists of term loans under a credit agreement (the “Credit Agreement”) and comprises of three trenches: (a) $15 million funded at closing (the “Tranche 1 Loan”), (b) $20 million funded on December 17, 2019 (the “Tranche 2 Loan”) and (c) up to $15 million available after the closing date and prior to September 30, 2020 (the “Tranche 3 Loan”). The Tranche 2 Loan was borrowed following the FDA’s approval of the Company’s NDA for AMZEEQ (formerly known as FMX101) and listing of AMZEEQ in the FDA’s “Orange Book,” in addition to maintained its arrangements with a third party for the commercial supply and manufacture of AMZEEQ. The Company shall be permitted to borrow the Tranche 3 Loan only following the achievement of certain revenue targets. Subject to any acceleration as provided in the Credit Agreement, including upon an event of default (as defined in the Credit Agreement), the credit facility will mature on July 29, 2024 and bear interest equal to the sum of (A) 8.25% (subject to increase in accordance with the terms of the Credit Agreement) plus (B) the greater of (x) the one-month LIBOR as of the second business day immediately preceding the first day of the calendar month or the date of borrowing (if such loan is not outstanding as of the first day of the calendar month), as applicable, and (y) 2.75%. A fee in an amount equal to 1.0% of the aggregate principal amount of all loans made on any given borrowing date shall be payable to the lenders.

The Credit Agreement is secured by a first-priority lien and security interest in substantially all of the Company’s tangible and intangible assets including intellectual property.

The Credit Agreement contains certain financial covenants, including that the Company (1) at all times after the date of FDA approval of AMZEEQ maintain a minimum aggregate compensating cash balance of $2.5 million; and (2) as of the last day of each fiscal quarter commencing on the fiscal quarter ending September 30, 2020, receive revenue for the trailing 12-month period in amounts set forth in the Credit Agreement, which range from $10.5 million for the fiscal quarter ending September 30, 2020 to $109.5 million for the fiscal quarter ending September 30, 2024.

As of December 31, 2019, the Company is in compliance with all covenants, including maintaining a minimum aggregate compensating cash balance as mentioned above. In the event where the Company fails to observe or perform any of the financial covenants the lenders may, by notice to the Company, declare the Term Loans then outstanding to be due and payable in whole, together with accrued interest and a Prepayment Premium (as defined in the Credit Agreement).

Under the Credit Agreement, there are no required payments of principal amounts until July 2023. Afterwards, the Company will pay 1.5% of the aggregate principal amount each month. The outstanding amount will be paid in full on July 2024.

In addition to the Credit Agreement, on the Closing Date, the Company issued to the lenders warrants to purchase up to an aggregate of 1,100,000 of its Ordinary Shares, at an exercise price of $2.09 per share (the “Warrant”), which represents the five-day volume weighted average price of the Ordinary Shares as of the trading day immediately prior to the Closing Date. Payment of the exercise price will be made, at the option of the lender, either in cash or as a reduction of Ordinary Shares issuable upon exercise of the Warrant, with an aggregate fair value equal to the aggregate exercise price ("cashless exercise"), or any combination of the foregoing. The Warrants were exercisable immediately following the closing of the Credit Agreement and are due to expire on July 29, 2026. Any Warrants left outstanding will be cashless exercised on the Warrants' expiration date, if in the money. The Warrants issued were classified as equity in accordance with ASC 815-40. Proceeds received under the Tranche 1 Loan were allocated to the Warrants and the Tranche 1 Loan on a relative fair value basis.

NOTE 10 – LONG-TERM DEBT (continued):

The company incurred offering expenses of $1,090 in connection with transactions contemplated by the Credit Agreement and the Securities Purchase Agreement, which were allocated to the Warrants, shares and debt consistently with the allocation of proceeds. The Company incurred additional expenses in the amount of $293 from the borrowing of Tranche 2 Loan, allocated only to the debt.

Debt issuance costs are recorded on the consolidated balance sheet as a reduction of liabilities.

Amounts allocated to the debt, net of issuance cost, are subsequently recognized at amortized cost using the effective interest method.

The fair value of the debt as of December 31, 2019 was $36.6 million and is categorized as Level 3. The valuation was performed by applying the income approach, under which the contractual present value method was used. The estimation of risk adjusted discount curve was based on public information reported in the financial statements of publicly traded venture lending companies.

During the year ended December 31, 2019 the company recorded finance expense of $802 and $119 relating to the interest and discount cost, respectively.

NOTE 11 - 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.

Following the Merger (see Note 1) Ordinary Shares were deemed transferred to Menlo in exchange for the right to receive (i) 0.5924 shares of common stock of Menlo Common Stock and (ii) one CSR. All outstanding Options and RSUs were converted using the Exchange Ratio and exercise price of the new options will be calculated by dividing the old exercise price by the Exchange Ratio. The Exchange Ratio is subject to adjustment based on the outcome and timing of the top-line primary endpoint results of one or both Melo's Phase III double-blinded, placebo-controlled trials for the treatment of pruritus associated with prurigo nodularis, referenced by Protocol Numbers MTI-105 (United States) and MTI-106 (Europe).

b. Warrants

In May and June 2014, the Company issued to certain investors Warrant to purchase Ordinary Shares at an exercise price of $5.04 per share or through a cashless exercise. As defined in the warrant agreements, the Warrants were exercisable until May 13, 2018. On that date all outstanding warrants were automatically exercised by the Warrant holders on a net issuance basis.

In addition to the Credit Agreement signed on July 29, 2019, on the Closing Date, the Company issued to the lender Warrants to purchase up to an aggregate of 1,100,000 of its Ordinary Shares. The warrants were exercisable immediately following the closing of the Credit Agreement and are due to expire on July 29, 2026. Any Warrants left outstanding will be cashless exercised on the Warrants' expiration date, if in the money.

During the years ended December 31, 2018, and 2017 1,394,558 and 413,242 warrants were exercised into 178,468 and 191,793 Ordinary Shares, respectively. During the year ended December 31, 2019 no Warrant were exercised.

NOTE 11 - SHARE CAPITAL (continued):

c. Public offerings

On September 18, 2018, the Company completed a public offering in which 11,670,000 Ordinary Shares were sold at a price of $6.00 per share. Upon closing of the offering, the underwriters exercised their ‘green shoe’ option at full and purchased 1,750,500 additional Ordinary Shares. The net proceeds, including the underwriters' option, were approximately $75,356, after deducting underwriter’s discounts, commissions and other offering expenses.

d. Securities Purchase Agreement

On April 13, 2018, the Company entered into a Securities Purchase Agreement with an existing investor pursuant to which the Company agreed to issue and sell, in a registered offering, an aggregate of 2,940,000 Ordinary Shares at a purchase price of $5.50 per share. The net proceeds from the offering were $16,131 after deducting transaction expenses. The closing of the issuance and sale of these shares took place on April 16, 2018.

On July 29, 2019, pursuant to the Credit Agreement and Securities Purchase Agreement, the Company issued and sold, in a registered offering, an aggregate of 6,542,057 shares of the Company’s Ordinary Shares, at a purchase price of $2.14 per share, representing the closing share price on the last trading day prior to signing, for aggregate gross proceeds of approximately $14 million, before deducting issuance costs allocated as described in Note 10 above, in the amount of $286.

e. Share Based Compensation

Equity incentive plan:

On April 10, 2019, the Company's shareholders approved a new equity incentive plan (the "Plan") replacing the prior equity plans approved in 2015 and 2009. The Plan included a pool of 6,027,990 Ordinary Shares for grant to Company employees, consultants, directors and other service providers. As of December 31, 2019, 5,215,508 shares remain available for grant under the Plan.

Employee Share Purchase Plan:

On April 10, 2019 the Company’s shareholders approved an ESPP pursuant to which qualified employees (as defined in the ESPP) may elect to purchase designated shares of the Company’s Ordinary Shares at a price equal to 85% of the lesser of the fair market value of Ordinary Shares at the beginning or end of each semi-annual share purchase period (“Purchase Period”). Employees are permitted to purchase the number of shares purchasable with up to 15% of the earnings paid (as such term is defined in the ESPP) to each of the participating employees during the Purchase Period, subject to certain limitations under Section 423 of the U.S. Internal Revenue Code.

The number of Ordinary Shares initially reserved for purchase under the ESPP was 5,400,000 Ordinary Shares. As of December 31, 2019, 5,265,551 shares remain available for grant under the ESPP.

During the year ended December 31, 2019 134,449 shares were issued to the employees.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 11 - SHARE CAPITAL (continued):

Options and RSUs granted to employees and directors:

In the years ended December 31, 2019, 2018 and 2017, the Company granted options as follows:

	Year ended December 31, 2019			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees and Directors:				
Options	1,635,296	$ 2.36- $3.88	1 year -4 years	10 years
RSU	425,604	-	1 year -4 years	-

	Year ended December 31, 2018			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees and Directors:				
Options	895,903	$ 4.06- $6.40	1 year -4 years	10 years
RSU	216,673	-	3 year -4 years	-

	Year ended December 31, 2017			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees and Directors:				
Options	1,352,267	$ 4.69- $10.31	4 years	10 years
RSU	370,091	-	4 years	-

The fair value of options and RSUs granted during 2019, 2018 and 2017 was $4,394, $3,953 and $8,510, respectively.

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 expected term of each option as its expected life. The expected term of the options granted represents the period of time that granted options are expected to remain outstanding.

The fair value of RSUs granted to employees and directors is based on the share price on grant date and was computed using the Black-Scholes model.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 11 - SHARE CAPITAL (continued):

The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31		
	2019	**2018**	**2017**
Value of ordinary share	$ 2.66-$3.88	$ 4.09-$5.99	$ 4.44-$10.12
Dividend yield	0%	0%	0%
Expected volatility	59.35%-61.4%	61%-62.6%	58.41%-61.7%
Risk-free interest rate	1.42%-2.62%	2.75%-2.87%	1.97%-2.16%
Expected term	6 years	6 years	6 years

Options and RSUs granted to consultants and service providers:

During the years ended December 31, 2019 and 2018 there were no grants of options and RSUs to consultants and service providers.

In the year ended December 31, 2017, the Company granted options as follows:

	Year ended December 31, 2017			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Options	4,800	$ 6.34	4 years	10 years

The total unrecognized share-based compensation cost at December 31, 2019 is $7,220, which is expected to be recognized over a weighted average period of two years.

Modification of share-based compensation:

During the year ended December 31, 2017 the Company performed a Type III modification for share-based compensation due to the retention of the options and RSUs for several employees (including Dr. Dov Tamarkin, former Chief Executive Officer and Mr. Meir Eini, Chief Innovation Officer) who have become consultants to the Company. As a result of the modification, during the year ended December 31, 2017, the Company reversed all expense previously recorded for these retained awards in the amount of $2,037 and recorded the additional compensation expense in the amount of $1,058 over the new requisite service period.

During the year ended December 31, 2018 the Company recorded additional share-based compensation expenses in the amount of approximately $690 with respect to Type III modification.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 11 - SHARE CAPITAL (continued):

Summary of outstanding and exercisable options and RSUs:

The following table summarizes the number of options outstanding for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, and related information:

	Employees and directors		Consultants and service providers	
	Number of options	USD(1)	Number of options	USD(1)
Outstanding at January 1, 2017	2,377,092	$ 5.87	137,050	$ 2.81
Granted	1,352,267	7.47	-	-
Forfeited	(39,213)	7.93	(8,800)	8.40
Exercised	(61,881)	2.63	-	-
Re-designated(2)	(252,210)	7.71	252,210	7.71
Outstanding at December 31, 2017	3,376,055	$ 6.41	380,460	$ 5.93
Granted	895,903	5.61	-	-
Forfeited	(150,240)	7.98	(41,697)	8.12
Exercised	(24,625)	1.92	(67,500)	0.05
Outstanding at December 31, 2018	4,097,093	$ 6.20	271,263	$ 7.05
Granted	1,635,296	3.39	-	-
Forfeited	(72,278)	6.78	(15,625)	7.98
Exercised	(298,682)	1.12	(18,125)	1.31
Re-designated(2)	(46,662)	7.58	46,662	7.58
Outstanding at December 31, 2019	5,314,767	$ 5.60	284,175	$ 7.45

(1) Weighted average price per share
(2) Pursuant to change in status of grantees from ‘employee’ and ‘director’ to ‘consultant’ during the reporting period.

The following table summarizes the number of RSUs outstanding for the years ended December 31, 2019, December 31, 2018 and December 31, 2017:

	Employees and directors	Consultants and service providers
	Number of RSUs	
Outstanding at January 1, 2017	142,683	42,050
Awarded	370,091	-
Forfeited	(4,025)	(550)
Vested	(43,038)	(33,625)
Re-designated(1)	(78,120)	78,120
Outstanding at December 31, 2017	387,591	85,995
Awarded	216,673	-
Forfeited	(11,746)	(12,150)
Vested	(161,648)	(60,271)
Outstanding at December 31, 2018	430,870	13,574
Awarded	425,604	-
Forfeited	(9,159)	-
Vested	(225,687)	(10,405)
Re-designated(1)	(10,199)	10,199
Withholding of shares	(9,775)	-
Outstanding at December 31, 2019	601,654	13,368

(1) Pursuant to change in status of grantees from ‘employee’ and ‘director’ to ‘consultant’ during the reporting period.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 11 - SHARE CAPITAL (continued):

The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2019:

	December 31, 2019			
	Options outstanding		Options exercisable	
Exercise prices per share (USD)	Number of options outstanding at end of year	Weighted Average Remaining Contractual Life	Number of options exercisable at end of year	Weighted Average Remaining contractual Life
1.92-3.88	1,723,515	8.91	234,749	6.34
4.06-6.18	1,526,944	7.24	1,024,250	6.90
6.30-7.98	1,682,087	6.17	1,406,840	5.83
8.55-11.87	666,396	6.50	506,540	6.30
	5,598,942		3,172,379	

The aggregate intrinsic value of the total of both the outstanding and exercisable options as of December 31, 2019, is $721.

Share-based compensation expenses:

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31		
	2019	2018	2017
Cost of revenues	$ -	$ -	$ 2
Research and development expenses	1,564	2,054	1,711
Selling, general and administrative	3,331	3,266	2,453
	$ 4,895	$ 5,320	$ 4,166

NOTE 12 - 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 24% in 2017 and 23% in 2018 and thereafter.

2) Effective January 1, 2018, the U.S. Tax Cuts and Jobs Act, reduced the U.S. federal statutory tax rate from 35% in 2017 to 21%.

b. Tax assessments

Foamix has tax assessments that are considered to be final through tax year 2014.

c. Tax benefits under the Law for Encouragement of Industry (Taxation), 1969

Foamix 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.

Foamix utilizes this tax benefit.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 12 - INCOME TAX (continued):

d. Loss before income tax taxes:

Loss (income) before income taxes is composed of the following:

	Year ended December 31		
	2019	**2018**	**2017**
Foamix Pharmaceuticals Ltd	$ 66,747	$ 71,925	$ 64,952
Foamix Pharmaceuticals Inc	28,607	2,026	(401)
Total Loss before taxes	$ 95,354	$ 73,951	$ 64,551

e. Losses for tax purposes carried forward to future years

As of December 31, 2019, Foamix had approximately $224.4 million and $27.3 million of net carry forward tax losses in Israel and the U.S., respectively, which are available to reduce future taxable income with no limited period of use.

During the year ended December 31, 2019 the U.S. Subsidiary incurred tax income of $176. During the years ended December 31, 2018 and 2017, the U.S. Subsidiary incurred a tax expense in the amount of $212 and $1,164, respectively.

f. Deferred income taxes:

	December 31,	
	2019	**2018**
In respect of:		
Net operating loss carry forward	$ 59,241	$ 33,859
Research and development	10,089	12,932
Share based compensation	1,446	957
Other	225	164
Less - valuation allowance	(71,001)	(47,912)
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.

As of December 31, 2019, the Company had no intention of realizing its investment in the Subsidiary and therefore deferred taxes have not been provided on taxes that would apply in the event of disposal of the investments.

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.

(U.S. dollars in thousands, except share and per share amounts)

NOTE 12 - INCOME TAX (continued):

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		
	2019	**2018**	**2017**
Loss before income taxes	$ 95,354	$ 73,951	$ 64,551
Theoretical tax benefit on the above amount	(21,931)	(17,009)	(15,492)
Decrease (increase) in tax refund resulting from:			
Reduction and different corporate tax rates	(1,430)	(101)	711
Non-deductible expenses and other permanent differences, mainly share based compensation expenses and issuance costs	225	(84)	80
Uncertain tax position	(176)	(98)	988
Net change in valuation allowance	23,089	17,063	14,858
Other	47	441	19
Actual tax expense	$ (176)	$ 212	$ 1,164

g. Uncertain tax positions:

ASC No. 740, Income Taxes, requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company.

The following table summarizes the activity of the Company unrecognized tax benefits:

Balance at January 1, 2018	$ 988
Decrease in uncertain tax positions for the year	(98)
Balance at December 31, 2018	$ 890
Decrease in uncertain tax positions for the year	(176)
Balance at December 31, 2019	$ 714

h. Roll forward of valuation allowance:

Balance at January 1, 2017	$ 15,991
Additions	14,858
Balance at December 31, 2017	$ 30,849
Additions	17,063
Balance at December 31, 2018	$ 47,912
Additions	23,089
Balance at December 31, 2019	$ 71,001

(U.S. dollars in thousands, except share and per share amounts)

NOTE 13 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31	
	2019	**2018**
a. Other current assets:		
Institutions	$ 471	$ 446
Prepaid expenses	1,038	450
Other	48	103
	$ 1,557	$ 999

Statements of operations:

b. Revenues

The Company is entitled to royalty payments with respect to sales of a product developed by a customer in collaboration with the Company (“the Product”).

During 2018, a new customer acquired the Product and assumed all rights and responsibilities under the initial agreement.

As of December 31, 2019, the Company has yet to record revenues from the sale of AMZEEQ.

The following table provides a breakdown of the Company’s net revenues:

	Year ended December 31		
	2019	**2018**	**2017**
Development Service Payments	$ -	$ 62	$ 140
Royalties	443	3,533	3,529
Total revenues	$ 443	$ 3,595	$ 3,669

c. Finance income and expenses:

	Year ended December 31		
	2019	**2018**	**2017**
Finance expenses:			
Interest and finance expenses on long-term debt	$ 921	$ -	$ -
Foreign exchange losses, net	213	27	57
Other expenses	19	17	14
Total finance expenses	1,153	44	71
Finance income:			
Gains from securities, net	(1,083)	(688)	(602)
Interest on bank deposits	(589)	(297)	(532)
Total finance income	$ (1,672)	$ (985)	$ (1,134)

(U.S. dollars in thousands, except share and per share amounts)

NOTE 14 - ENTITY-WIDE DISCLOSURE:

Revenues from principal customers - revenues from single customers that exceed 10% of total revenues in the relevant year:

	Year ended December 31		
	2019	**2018**	**2017**
Customer A	$ -	$ 2,467	$ 3,529
Customer B	$ 443	$ 1,066	$ -

NOTE 15 – MENLO MERGER

On March 9, 2020, the Merger of Foamix with Menlo Merger Sub was completed, and the Company is now a wholly-owned subsidiary of Menlo, the legal acquirer (See note 1).

The Merger will be accounted in accordance with Accounting Standards Codification Topic 805, “Business Combinations”, using the acquisition method of accounting with Foamix as the accounting acquirer. Since Menlo, as the parent company of Foamix after the Merger, is the legal acquirer, the Merger will be accounted for as a reverse acquisition.

As the Merger was completed subsequent to December 31, 2019, the consolidated financial statements do not include the results or the financial position of Menlo.

Under the disclosure requirements of ASC 805 the Company is required to provide information regarding the effect of the business combination.

Due to the following limitations, the initial accounting for the business combination was incomplete at the time of the issuance of the financial statements, therefore, the Company did not include the above mentioned information as permitted by ASC 805-10-50-4 and ASC 805-30-50-3.

1) As described above, the acquisition was completed on March 9, 2020, while the filing date the Company’s annual financial statements in form 10-K is March 12, 2020.

2) Full and final financial data of Menlo was available to the Company only on March 3, 2020 following the filing of Menlo’s form 10-K.

3) The Company hasn’t completed the work of the purchase price allocation needed under ASC 805.

Supplemental Financial Information

Unaudited selected quarterly financial results for the years ended December 31, 2019 and 2018 were as follows:

	2019				2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	$ 308	$ -	$ -	$ 135	$ 906	$ 964	$ 865	$ 860
Cost of revenues	-	-	-	-	-	-	-	-
Gross profit	308	-	-	135	906	964	865	860
Operating loss	15,884	19,359	23,199	37,431	25,720	18,787	15,586	14,799
Loss per share basic and diluted	$ 0.28	$ 0.35	$ 0.41	$ 0.63	$ 0.69	$ 0.46	$ 0.38	$ 0.26

ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the company’s management, including its chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, 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, 2019. Based on such evaluation, those officers have concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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) under the Exchange Act 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 (a) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) 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 (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting, as of December 31, 2019. 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 concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on these criteria. The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Kesselman & Kesselman, an independent registered public accounting firm in Israel and a member of PricewaterhouseCoopers International Limited ("PwC"), as stated in their report which is included under "Item 8—Financial Statements."

ITEM 9B - OTHER INFORMATION

None.

PART III

ITEM 10 - DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

This item has been omitted in reliance on General Instruction I(1)(a) and (b) of Form 10-K.

ITEM 11 - EXECUTIVE COMPENSATION

This item has been omitted in reliance on General Instruction I(1)(a) and (b) of Form 10-K.

ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

This item has been omitted in reliance on General Instruction I(1)(a) and (b) of Form 10-K.

ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

This item has been omitted in reliance on General Instruction I(1)(a) and (b) of Form 10-K.

ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES

Kesselman & Kesselman (a member firm of PricewaterhouseCoopers International Limited, or PwC), served as our principal independent registered public accounting firm for each of the two years ended December 31, 2018 and 2019.

The following table provides information regarding fees paid by us to PwC for all services, for the years ended December 31, 2018 and 2019:

	Fiscal year ended December 31,	
	2019	2018
	(in thousands of U.S. dollars)	
Audit fees[1]	$ 428	$ 193
Audit-related fees	-	-
Tax fees[2]	9	-
All other fees	-	-
Total Fees	$ 437	$ 193

(1) Includes professional services rendered in connection with the audit of our annual financial statements, the review of our interim financial statements and fees for registration statements.

(2) Includes professional services rendered in connection with assistance in preparation of applications to the Israel Tax Authorities.

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee pre-approves all non-audit services provided to the Company during year.

PART IV

ITEM 15 - EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents Filed as Part of This Report

1. ***Financial statements***.

See Index to Financial Statements under Item 8 of Part II of this Annual Report, which is incorporated herein by reference.

2. ***Financial statement schedules***.

No schedules are applicable or required, or the information is included in the consolidated financial statements or notes thereto.

3. ***Exhibits***. See Item 15(b) below.

(b) Exhibits

		Incorporation by Reference				
Exhibit Number	Description Of Document	Form	SEC File No.	Exhibit	Filing Date	Filed Herewith
2.1*	Agreement and Plan of Merger, dated as of November 10, 2019, by and among Foamix Pharmaceuticals Ltd., Menlo Therapeutics Inc. and Giants Merger Subsidiary Ltd.	8-K	001-36621	2.1	November 12, 2019	
2.2	Amendment No. 1 to the Agreement and Plan of Merger, dated as of December 4, 2019, by and among Foamix Pharmaceuticals Ltd., Menlo Therapeutics Inc. and Giants Merger Subsidiary Ltd.	8-K	001-36621	2.1	December 4, 2019	
3.1	Amended and Restated Articles of Association of the Company	10-Q	001-36621	3.1	May 7, 2019	
4.1	Specimen Ordinary Share Certificate of the Registrant	F-1/A	333-198123	4.1	September 3, 2014	
4.2	Description of Securities Registered Under Section 12 of the Exchange Act					X
10.1#	2009 Israeli Share Option Plan	F-1/A	333-198123	10.1	September 3, 2014	
10.2#	2015 Israeli Share Incentive Plan	F-3	333-207546	10.2	October 21, 2015	
10.3#	2019 Equity Incentive Plan	8-K	001-36621	10.1	April 11, 2019	
10.4#	Form of U.S. Share Option Grant Notice and Option Agreement under the Foamix Pharmaceuticals Ltd. 2019 Equity Incentive Plan	10-Q	001-36621	10.4	May 7, 2019	
10.5#	Form of U.S. Restricted Share Unit Grant Notice and Restricted Share Unit Award Agreement under the Foamix Pharmaceuticals Ltd. 2019 Equity Incentive Plan	10-Q	001-36621	10.5	May 7, 2019	
10.6#	Forms of Israeli Share Option Agreement, Share Option Grant Notice, Restricted Share Unit Grant Notice and Restricted Share Unit Award Agreement under the Foamix Pharmaceuticals Ltd. 2019 Equity Incentive Plan.	S-8	333-230942	99.3	April 18, 2019	
10.7#	2019 Employee Share Purchase Plan	8-K	001-36621	10.2	April 11, 2019	
10.8	Summary of Lease Agreement, dated as of May 7, 2008, as amended on April 18, 2016, by and between the Registrant and Gav Yam Real Estate Ltd.	10-K	001-36621	10.3	February 28, 2019	

10.9#	Form of Indemnification Agreement by and between the Registrant and each of its directors	F-1/A	333-198123	10.3	September 3, 2014
10.10#	Foamix Pharmaceuticals Ltd. Amended Compensation Policy for Officers and Directors	10-K	001-36621	10.5	February 28, 2019
10.11#	Employment Agreement by and between Foamix Pharmaceuticals Inc. and David Domzalski, dated November 27, 2017	10-K	001-36621	10.6	February 28, 2019
10.12#	Employment Agreement by and between Foamix Pharmaceuticals Ltd. and Ilan Hadar, dated September 13, 2017	10-K	001-36621	10.7	February 28, 2019
10.13#	Form of Amendment to Employment Agreement Between Foamix Pharmaceuticals Ltd. and Ilan Hadar	10-Q	001-36621	10.3	May 7, 2019
10.14#	Offer Letter Agreement by and between Foamix Pharmaceuticals Inc. and Mutya Harsch, dated November 17, 2018	10-K	001-36621	10.8	February 28, 2019
10.15#	Amendment to Offer Letter Agreement Between Foamix Pharmaceuticals Inc. and Mutya Harsch	10-Q	001-36621	10.2	May 7, 2019
10.16	Lease Agreement, dated as of October 25, 2017, between Foamix Pharmaceuticals Inc. and S/K 520 Associates	10-K	001-36621	10.9	February 28, 2019
10.17	Credit Agreement and Guaranty among Foamix Pharmaceuticals Inc., Foamix Pharmaceuticals Ltd., Perceptive Credit Holdings II, LP, OrbiMed Royalty & Credit Opportunities III, LP and the other lenders from time to time party thereto	10-Q	001-36621	10.1	November 12, 2019
10.18	U.S. Security Agreement among Foamix Pharmaceuticals Inc., Foamix Pharmaceuticals Ltd. and Perceptive Credit Holdings II, LP for the benefit of Perceptive Credit Holdings II, LP, OrbiMed Royalty & Credit Opportunities III, LP and the other lenders from time to time party to the Credit Agreement	10-Q	001-36621	10.2	November 12, 2019
10.19	Warrant Certificate issued by Foamix Pharmaceuticals Ltd. for the benefit of OrbiMed Royalty & Credit Opportunities III, LP	10-Q	001-36621	10.3	November 12, 2019
10.20	Warrant Certificate issued by Foamix Pharmaceuticals Ltd. for the benefit of Perceptive Credit Holdings II, LP	10-Q	001-36621	10.4	November 12, 2019
10.21	Securities Purchase Agreement, dated July 29, 2019, by and among Foamix Pharmaceuticals Ltd. and Perceptive Life Sciences Master Fund, Ltd.	8-K	001-36621	10.1	July 30, 2019

10.22	Controlled Equity Offering Sales Agreement[SM], dated August 19, 2019, by and between Foamix Pharmaceuticals Ltd. and Cantor Fitzgerald & Co.	8-K	001-36621	1.1	August 19, 2019	
10.23	Form of Menlo Voting Agreement, dated November 10, 2019, by and between Foamix Pharmaceuticals Ltd. and certain stockholders of Menlo Therapeutics Inc.	8-K	001-36621	10.1	November 12, 2019	
10.24	Form of Foamix Voting Agreement, dated November 10, 2019, by and between Menlo Therapeutics Inc. and certain shareholders of Foamix Pharmaceuticals Ltd.	8-K	001-36621	10.2	November 12, 2019	
10.25	Form of CSR Agreement	8-K	001-36621	10.3	November 12, 2019	
10.26*	Contract Manufacturing and Supply Agreement, dated October 21, 2019, by and between Foamix Pharmaceuticals Ltd. and ASM Aerosol-Service AG.					X
21.1	List of Subsidiaries of Foamix Pharmaceuticals Ltd.					X
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Document					X
101.LAB	XBRL Taxonomy Extension Label Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

* Exhibits and schedules omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted exhibit or schedule will be furnished supplementally to the SEC upon request.

Indicates management contract or compensatory plan.

ITEM 16 - FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Foamix Pharmaceuticals Ltd. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 9, 2020.

FOAMIX PHARMACEUTICALS LTD.

By: /s/ David Domzalski
David Domzalski
Chief Executive Officer

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Domzalski and Ilan Hadar, and each of them, his or her attorney-in-fact and agent, each with the power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or his or her or their substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Signature	Title	Date
/s/ David Domzalski David Domzalski	Director and Chief Executive Officer (*Principal Executive Officer*)	March 12, 2020
/s/ Ilan Hadar Ilan Hadar	Director and Chief Financial Officer (*Principal Financial Officer* and *Principal Accounting Officer*)	March 12, 2020
/s/ Mutya Harsch Mutya Harsch	Director	March 12, 2020

Exhibit 4.2

FOAMIX PHARMACEUTICALS LTD.

DESCRIPTION OF ORDINARY SHARES

As of December 31, 2019

As of December 31, 2019, the ordinary shares, par value NIS 0.16 per share, (the "Ordinary Shares") of Foamix Pharmaceuticals Ltd. ("Foamix") were listed on the Nasdaq Global Stock Market ("Nasdaq") under the symbol "FOMX." As of March 9, 2020, all Ordinary Shares are owned by Menlo Therapeutics Inc. and no longer trade on the Nasdaq.

The following description of the terms of the Ordinary Shares is as of December 31, 2019 and is not complete and is qualified in its entirety by reference to our Amended and Restated Articles of Association which is an exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. You should also refer to the Israeli Companies Law for a complete statement of the terms and rights of the Ordinary Shares.

Voting Rights

The Ordinary Shares confer on the holders thereof the right to attend and to vote at general meetings, both annual as well as extraordinary meetings. The holders of the Ordinary Shares are entitled to one vote per share. All resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law or by our Amended and Restated Articles of Association.

Dividend and Liquidation Rights

Dividends may be declared by Foamix's board of directors in cash or bonus shares. Dividends must be paid or distributed, as the case may be, equally to the holders of the Ordinary Shares registered in Foamix's share register, pro rata to the par value of the Ordinary Shares, without reference to any premium which may have been paid thereon. Dividends may be paid only out of Foamix's profits and other surplus funds, as defined in the Israeli Companies Law, as of the end of the most recent year or as accrued over a period of the most recent two years, whichever amount is greater, provided that there is no reasonable concern that payment of a dividend will prevent Foamix from satisfying its existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of the Ordinary Shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Other Rights

The Ordinary Shares are not redeemable and do not have any preemptive rights.

Anti-Takeover Measures under Israeli Law

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to the Ordinary Shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. Currently there are no preferred shares authorized under our Amended and Restated Articles of Association. 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 a majority of the votes cast by shareholders who are present and voting at a general meeting, disregarding abstentions.

Exhibit 10.26

CONTRACT MANUFACTURING AND SUPPLY AGREEMENT

FOAMIX PHARMACEUTICALS LTD.
ASM AEROSOL-SERVICE AG

Table of Contents

This Contract Manufacturing and Supply Agreement is entered into as of October 18, 2019 (the "**Effective Date**") by and between:

Foamix Pharmaceuticals Ltd., a company duly organized and existing under the laws of Israel,

whose registered office is 2 Holzman Street, Rehovot Science Park, Rehovot, Israel

– hereinafter "**FOAMIX**" –

X

and

ASM Aerosol-Service AG a company incorporated and existing under the laws of Switzerland with its principal place of business at Industriestrasse 11, 4313 Möhlin, Switzerland

– hereinafter "**ASM**" –

X

PREAMBLE

FOAMIX has developed the Products and owns or controls the Intellectual Property in the Products for the Territory; ASM has the requisite knowledge, expertise and resources to Manufacture the Products for and on behalf of FOAMIX;

The Intellectual Property of the Manufacturing Process belongs to FOAMIX;

FOAMIX wishes ASM to Manufacture the Products based on the terms and conditions of this Agreement, and ASM agrees to Manufacture the Products on such terms and conditions;

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1. DEFINITIONS

Unless otherwise expressly stated, or the context otherwise requires, the words and expressions listed below shall, when used in this Agreement, including this clause 1, bear the meanings ascribed to them:

1.1 **Additional Period** – has the meaning set forth in clause 2.2;

1.2 **Affiliate** – with respect to each Party, any corporation, firm, partnership or other legal entity that directly or indirectly is controlled by, controls or is under common control with such Party. For purposes of this definition, "control" means, with respect to such entity, the direct or indirect ownership of more than fifty percent (50%) of the voting interest in such entity or the possession **otherwise**, directly or indirectly, of the power to direct the management or policies of such entity;

1.3 **Agreement** – this Contract Manufacturing and Supply Agreement, including its Appendices;

1.4 **Aggrieved Party** – Has the meaning set forth in clause 22.2;

1.5 **API** – Means the active pharmaceutical ingredient of a Product;

1.6 **Appendix** – An appendix to this Agreement;

1.7 **ASM Developed IP** – Has the meaning set forth in clause 20.3;

1.8 **Background IP** – Has the meaning set forth in clause 20.1;

1.9 **Business Day** – Shall mean any day other than Saturday, Sunday or a public holiday in either (i) Switzerland (if the obligor is FOAMIX) or (ii) the United States or Israel (if the obligor is ASM).

1.10 **CGMP** – Means, the then-current Good Manufacturing Practices for medicinal products that is applicable to the manufacture of a Product, including in the United States.

1.11 **Confidential Information** – All information of whatsoever nature (whether oral, written, electronic or in any other form) including data, know-how, trade secrets, manufacturing processes and systems, samples of goods, software techniques, procedures, test methods, unpublished financial statements and information, licenses, prices, price lists, pricing policies, customer and supplier lists, customer and supplier names and other information relating to customers and suppliers, marketing techniques and marketing development tactics and plans, and all other information containing or consisting of material of a technical, operational, administrative, economic, marketing, planning, business or financial nature or in the nature of Intellectual Property, in each case, disclosed (i) by FOAMIX or any Affiliate of FOAMIX to ASM or any of its employees, agents or contractors, or disclosed by ASM to FOAMIX or any of its Affiliates, or its or their employees, agents or contractors and (ii) under this Agreement or the Development Agreement. For clarity, (A) Foamix API Material, Foamix API Material Specifications, Foamix Background IP and Foamix Developed IP shall be deemed Confidential Information of Foamix, and (B) ASM Background IP and ASM Developed IP shall be deemed Confidential Information of ASM;

1.12 **Defaulting Party** – Has the meaning set forth in clause 22.2;

1.13 **Defective Product** – Has the meaning set forth in clause 17.6;

1.14 **Development Agreement** – The Development Agreement by and between the Parties dated as of February 5, 2015;

1.15 **Disclosing Party** – Has the meaning set forth in clause 26.1;

1.16 **Facility** – The pharmaceutical production facilities of ASM situated at 4313 Möhlin, Switzerland;

1.17 **FOAMIX Developed IP** – Has the meaning set forth in clause 20.2;

1.18 **FOAMIX API Material** – The active pharmaceutical ingredient minocycline hydrochloride, to be supplied by FOAMIX to ASM for Manufacture of the Products;

1.19 **FOAMIX API Material Specifications** – The specifications for the manufacture, testing, storage, handling and packaging of FOAMIX API Material agreed to by the Parties and set forth Appendix 2 (Quality Agreement);

1.20 **Forecast** – Has the meaning set forth in clause 7.1.1;

1.21 **Governmental Approval** – Any approval, waiver, exemption, variance, permit, authorization, license, registrations or similar approval of any Governmental Authority necessary for the Manufacture of the Product;

1.22 **Governmental Authority** – Any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity that has the responsibility, jurisdiction and authority to approve the manufacture, use, importation, packaging, labelling, marketing and sale of pharmaceutical products in any country or jurisdiction;

1.23 **Indemnitee** – Has the meaning set forth in clause 19.3;

1.24 **Indemnitor** – Has the meaning set forth in clause 19.3;

1.25 **Initial Period** – Has the meaning set forth in clause 2.1;

1.26 **Intellectual Property** – Each of the following: (i) copyrights, trademarks, trade secrets, patent rights, supplementary patent certificates, patent extensions, know-how, concepts, database rights, and rights in trademarks, trade secrets and designs (whether registered or unregistered); (ii) applications for registration, and the right to apply for registration, for any of the same; (iii) all other intellectual property rights and equivalent or similar forms of protection existing anywhere in the world; (iv) inventions, developments, methods or processes, including any intellectual property rights in the foregoing, and (v) modifications or improvements to any of the items in clauses (i)-(iv);

1.27 **Losses** – Has the meaning set forth in clause 19.1;

1.28 **Manufacture / Manufacturing** – In relation to the Products, the manufacture, analytical testing (including release and stability testing), labelling, packaging, storage, release and delivery thereof;

1.29 **Manufacturing Process** – The technical process of manufacturing and/or packaging a Product according to the Specifications;

1.30 **Marketing Approval** – Has the meaning set forth in clause 13.4;

1.31 **Party / Parties** – "**Parties**" stands for both FOAMIX and ASM; "**Party**" means either of them, as the context may require;

1.32 **Price** – Has the meaning set forth in clause 9;

1.33 **Product Material** – Any raw materials, excipients, packaging materials or components used in the Manufacture of the Products other than the FOAMIX API Material, including as set forth on Appendix 7;

1.34 Products – The products listed in Appendix 1, to be manufactured by ASM in accordance with the Specifications and all other terms of this Agreement;

1.35 **Purchase Order** – Has the meaning given in clause 0;

1.36 **Quality Agreement** – The Quality Agreement set out in Appendix 2, between ASM and FOAMIX, which addresses technical and quality requirements as amended from time to time after agreement between the affected quality departments by the written agreement of ASM and FOAMIX. In case of differences or conflicts between this Agreement and the Quality Agreement, the Quality Agreement shall prevail solely for matters related to product quality and CGMP;

1.37 **Recall** – Any action by FOAMIX or any of its Affiliates to recover title to or possession of or to prevent the distribution, prescription, consumption or release of a Product sold or shipped to third parties, pursuant to a quality issue related to Manufacturing or testing of a Product or as required by an applicable Governmental Authority. The use of the term "**Product**" in the definition of "**Recall**" also includes Product which FOAMIX has not sold or delivered to third parties, but which would have been subject to recall if it had been sold or delivered;

1.38 **Receiving Party** – Has the meaning set forth in clause 26.1;

1.39 **Representative** – Has the meaning set forth in clause 26.2;

1.40 **Specifications** – those characteristics, formulae, manufacturing, testing, packaging, labelling, storage, standards and other specifications for such Product as set out in Appendix 2 (Quality Agreement), as the same may be amended or supplemented from time to time by mutual written agreement of the Parties;

1.41 **Supply Failure** – Has the meaning set forth in clause 8.4;

1.42 **Supply Interruption**– Has the meaning set forth in clause 8.4;

1.43 **Term** – Has the meaning given in clause 2.2;

1.44 **Territory** – Means worldwide, other than the countries Japan and China;

1.45 **Transport Costs** – Has the meaning given in clause 8.2.

2. COMMENCEMENT AND TERM

2.1 This Agreement shall commence on the Effective Date and continue for an initial period of four (4) years, unless terminated earlier as provided elsewhere in this Agreement ("**Initial Period**").

2.2 After the Initial Period, the Agreement will automatically renew for a further period of two (2) years, and for further periods of two (2) years thereafter (each an "**Additional Period**," and together with the Initial Period, the "**Term**"), unless terminated earlier as provided for in this Agreement.

3. AGREEMENT TO SUPPLY

3.1 During the Term of this Agreement and subject to the provisions of this Agreement, ASM shall Manufacture and supply to FOAMIX, and FOAMIX shall purchase from ASM the finished Products, in such quantities and on such dates as specified by FOAMIX and agreed upon by ASM as set forth in this Agreement. Other than as set forth in clauses 7.3 and 8.4, for four (4) years from the Effective Date, ASM shall Manufacture and supply all of FOAMIX's commercial needs for the Products in the Territory on an exclusive basis. Except in the case of material breach by FOAMIX under this Agreement, during the Term and for two (2) years after termination or expiration of this Agreement, ASM shall not manufacture or supply to a third party any topical product containing the active pharmaceutical ingredient minocycline or minocycline hydrochloride.

3.2 FOAMIX hereby instructs and authorizes ASM to manufacture the Products in accordance with the Manufacturing Process and FOAMIX's manufacturing instructions.

3.3 ASM shall source and supply all Product Materials for the Manufacturing of the Products and FOAMIX shall approve the procurement of the type and quality of the Product Materials needed for the Manufacturing of the Products prior to the procurement of such Product Materials and approve all artwork, advertising and labelling information necessary for Manufacturing the Products. Such artwork, advertising and labelling information is and shall remain the exclusive property of FOAMIX, and FOAMIX shall be solely responsible for the content thereof. Such material, components, artwork, advertising and labelling information or any reproduction thereof may not be used by ASM in any manner other than in performing its obligations hereunder.

3.4 All Manufacturing and storage of a Product until the delivery to FOAMIX of the finished Product shall be carried out by ASM at its Facility utilizing equipment, molds and tooling in the manner set forth in the Specifications. ASM is responsible for maintaining all equipment and tooling used to Manufacture the Product in good working condition, and at its own cost.

3.5 Foamix shall have the right during the Term, exercisable itself or through a third party contractor of its choosing, to engage in manufacturing activities related to the Products other than the manufacture of materials used for commercial supply of the Products; such permissible "manufacturing activities" shall include the conduct of process and cost optimization, process development, qualification and validation, equipment and facility qualification and validation, stability and release testing, quality assurance and quality control. For clarity, the conduct of the aforementioned activities shall not be deemed to be a violation of Foamix's obligations under this clause 3.

4. MANUFACTURE

4.1 ASM shall Manufacture the Products based on the terms and conditions set forth in this Agreement. All manufacturing operations shall be performed in strict compliance with: applicable laws and regulations; applicable CGMP; the Specification; the Quality Agreement; and the applicable laws and regulations on health, safety and environment protection.

4.2 Analysis of Materials

For the purposes of this Agreement, all quality control tests and analysis on raw materials, packaging materials, components and other Product Materials shall be considered routine and shall be performed in accordance with the Quality Agreement by ASM. Any additional tests expressly initiated or requested by FOAMIX shall be performed at FOAMIX's expense. All test results are to be documented in accordance with CGMP and will be available for audits at FOAMIX's request.

4.3 Quality Control and Records

4.3.1 ASM shall perform all tests (chemical and/or microbial) on the Product Materials and on the finished Product to ensure the quality of the Products as required by the Specifications and the Quality Agreement.

4.3.2 Any tests required to be performed by the Specifications or the Quality Agreement, including any in-process controls for such testing, shall be performed at ASM's expense and any external costs incurred by ASM for such quality control tests shall be passed-through to FOAMIX. Any additional tests expressly initiated or requested by FOAMIX beyond what is contained in the foregoing clause shall be performed at FOAMIX's expense.

4.3.3 ASM shall review all production records and the disposition of each batch of Products. ASM will maintain complete and accurate records relating to the Products and the Manufacture thereof and ASM shall provide copies thereof to FOAMIX upon request, including upon expiration or termination of this Agreement. The records shall be subject to audit and inspection under clause 12. The Quality Agreement further details the quality assurance obligations and responsibilities of the Parties.

5. COMMUNICATION AND AUTHORITY REQUESTS

5.1 If required, regular communications between designated representatives of the Parties shall be carried out to deal with the Manufacturing performance and its improvement. In addition, the Parties shall meet on a regular basis to discuss operational and performance issues, including but not limited to, demand planning for each Product and ASM's performance, the status of any key performance indicators and possible improvements.

5.2 FOAMIX is responsible to respond to all requests for information about the Products and the Manufacturing Process from any Governmental Authority and in making all legally required filings for purposes of obtaining and maintaining Marketing Approval. ASM shall provide reasonable assistance to FOAMIX. FOAMIX will promptly inform ASM of any regulatory changes that may impact the Manufacture of the Products. Additional costs will be discussed in good faith.

6. SUPPLY OF FOAMIX API MATERIAL AND OTHER PRODUCT MATERIAL

6.1 FOAMIX shall supply, or cause to be supplied to ASM at the Facility, at no cost to ASM, the quantity of FOAMIX API Material necessary to meet FOAMIX's Forecast. ASM shall use such API solely to Manufacture the Products.

6.2 FOAMIX shall deliver such items and associated certificates of analysis and certificate of compliance to ASM at the Facility. All FOAMIX API Material shall be delivered freight, insurance and duty paid at the Facility (DDP Möhlin Incoterms 2010). The FOAMIX API Material supplied by or on behalf of FOAMIX shall conform to the FOAMIX API Material Specification. ASM shall acknowledge the receipt of the FOAMIX API Material promptly and in writing within five (5) Business Days after receipt. Upon receipt, ASM shall promptly inspect the conformity of the FOAMIX API Material to the Specifications and test such items to verify their identity as per the Quality Agreement attached in Appendix 2, as further detailed in clause 6.5 below. If ASM detects a non-conformity with Specifications, certificate of analysis or certificate of compliance, ASM shall give FOAMIX prompt notice of such finding as further detailed in clause 6.5 below. ASM shall follow FOAMIX's instructions to return or dispose of any defective API; all costs associated therewith shall be borne by FOAMIX.

6.3 ASM shall inform FOAMIX of any damage to the FOAMIX API Material that is visible from the exterior of its packaging or of a shortage in the quantity of delivered FOAMIX API Material within five (5) Business Days of ASM's receipt of the FOAMIX API Material. FOAMIX should replace such damaged items or use commercially reasonable efforts to provide additional FOAMIX API Material to ASM in time so that any Purchase Order for which such FOAMIX API Material was destined can be Manufactured by ASM in accordance with this Agreement. ASM shall provide assistance in the investigation of any damaged items. ASM shall put damaged FOAMIX API Material under quarantine at FOAMIX's expense until the FOAMIX API Material is returned to FOAMIX or its designee. If FOAMIX fails to timely deliver or cause to be delivered FOAMIX API Material or replacement FOAMIX API Material, ASM shall not be liable under this Agreement for any failure to deliver Product by the required delivery date.

6.4 Title to all FOAMIX API Material supplied to ASM hereunder shall remain in FOAMIX. ASM shall mark such FOAMIX API Material as the property of FOAMIX and store it separate and apart from other materials that are not used to Manufacture the Products. ASM shall use the inventory of FOAMIX API Material in accordance with FEFO (first expiry, first out) principles to Manufacture the Products. At the end of each month, ASM shall provide, in a reasonably acceptable format that is compatible with the FOAMIX enterprise resource planning system, the quantity of FOAMIX API Material in its possession by FOAMIX API Material batch number, and the remaining shelf-life of such FOAMIX API Material. In addition to FOAMIX's right to audit the Facility under Section 12.1, ASM shall allow FOAMIX to participate in one annual routine physical inventory check of FOAMIX API Material at the Facility, as further described in clause 12.3.

6.5 ASM shall handle, sample and test the FOAMIX API Material in accordance with the FOAMIX API Material Specifications and in accordance with CGMP requirements. ASM shall inspect, at its own cost, each delivery of FOAMIX API Material in order to verify the conformity of the FOAMIX API Material with the FOAMIX API Material Specifications, as set forth in the Quality Agreement. ASM shall perform such inspection within thirty (30) calendar days after receipt of FOAMIX API Material, and in any case, prior to the use of the FOAMIX API Material in the Manufacture of the Products. Any out of Specification results from the FOAMIX API Material Specifications shall be investigated and reported to FOAMIX, as set forth in the Quality Agreement.

6.6 ASM shall procure at its own cost and expense, all Product Materials and provide all labor, facilities, equipment, machinery, heat, light and power, sufficient and necessary for the Manufacture and storage of the Products until delivery to FOAMIX. ASM shall procure such Product Materials from suppliers for which ASM has received prior written agreement from FOAMIX, as set forth in the Quality Agreement. For the avoidance of doubt, whether or not FOAMIX has approved or authorized a supplier shall have no effect upon ASM's liability for all Product Materials used by ASM hereunder. The Product Materials shall meet the Specifications approved and agreed upon by the Parties, if applicable. ASM shall perform quality control and assurance testing and evaluation of the Product Materials as required in accordance with the Quality Agreement to meet the foregoing obligation. ASM agrees to maintain all equipment, machinery and facilities in good working condition and in compliance with CGMP.

6.7 ASM shall order sufficient quantities of all Product Materials required to Manufacture and deliver the Products, and to have sufficient Product Materials on hand in order to be able to Manufacture and supply to FOAMIX its requirement of the Products for no less than the first six (6) months of each Forecast and as described in clause 7.1.2. In the event of (i) a Specification change by FOAMIX for any reason, (ii) obsolescence of any Product Material or (iii) termination or expiration of this Agreement, FOAMIX shall bear the cost of any unused Product Material, provided that such Product Material was ordered in accordance with this clause.

7. FORECASTS, PURCHASE ORDERS AND CAPACITY

7.1 Rolling Forecasts

7.1.1 On or before the last day of each month during the Term, FOAMIX shall provide to ASM a written rolling forecast (each, a "**Forecast**") of its Purchase Order volumes of each Product for each month in the subsequent twelve (12) month period. The volume referenced in the first four (4) months of each Forecast shall represent a binding obligation of FOAMIX to purchase from ASM, and for ASM to Manufacture and supply to FOAMIX, such quantities of Product. If FOAMIX submits Purchase Orders during such binding Forecast period to ASM that are in an amount below such binding volume, then ASM shall be entitled to invoice the difference to FOAMIX.

7.1.2 Following receipt of a Forecast, ASM undertakes to order and reserve sufficient capacity and quantities of such Product Materials to fulfill the Product requirements of FOAMIX as reflected in the first six (6) months of each Forecast plus the defined safety stock as mutually agreed to by the Parties.

7.1.3 By September 1st of each year during the Term, FOAMIX shall provide the annual Forecast for the immediately following calendar year to secure capacity for supply of the Products at the Facility. Following the receipt of the annual Forecast, the Parties shall act reasonably and in good faith to review any potential price adjustment in the Product Price, whether upward or downward, and any adjustment shall be agreed upon no later than October 31st with such adjusted price to become effective on January 1st of the immediately following calendar year. Subject to compliance with the Specifications, Quality Agreement and this Agreement, ASM shall use reasonable commercial efforts to work with FOAMIX to source Product Materials, external quality control and assurance services, and improve batch yields or fill volume in the Manufacturing process in a manner that shall reduce the Product Price pursuant to this clause. Any component or service price in the Product Materials or external quality control cost(s) that fluctuates by more than 10% of the then-existing price for such Product Material(s) or external quality control cost(s) (as demonstrated in the previous annual forecast) will require an immediate supply price adjustment to the itemized price for such Product Material or quality control cost in an amount that is equal to the difference in cost for such Product Material or quality control cost with no mark-up. Other than as set forth in the immediately preceding sentence, no Party shall be required to agree to an upward or downward adjustment in the Price.

7.2 Purchase Orders

7.2.1 FOAMIX shall place an order for Product through a written purchase order delivered to ASM from time to time to the email address as identified in clause 28.1 ("**Purchase Order**"). Each order of Products shall be supplied by ASM on the basis of a Purchase Order placed by FOAMIX. Purchase Orders shall supersede any previous verbal agreement between the Parties.

7.2.2 Each Purchase Order shall indicate the Purchase Order number, Product code, quantity ordered, required delivery date and delivery address. Each Purchase Order shall be placed in Swiss Francs (CHF). Any Purchase Order shall be based on the minimum order quantities set forth in Appendix 1.The specified delivery date for an order placed in the Purchase Order shall be no less than ninety (90) days after the date of such Purchase Order, unless otherwise agreed to by the Parties.

7.2.3 ASM shall acknowledge and confirm each Purchase Order within seven (7) Business Days of receipt including confirmation of the required delivery date and quantities by email. If ASM is unable to confirm the delivery date within these 7 days ASM shall confirm the reception of the Purchase Order. The delivery date shall be confirmed twenty (20) Business Days after receipt of the Purchase Order at the latest. If ASM does not confirm Purchase Order within this time, following reasonable commercial efforts on the part of FOAMIX to obtain such confirmation, the Purchase Order shall be deemed as confirmed by ASM. ASM shall supply the Product in accordance with each Purchase Order and the terms of this Agreement. Each Purchase Order confirmation shall include reference to only one (1) Purchase Order. Any change of a Purchase Order requires a revised Purchase Order and a revised order acknowledgement. Notwithstanding anything to the contrary in this Agreement, ASM shall not reject any Purchase Order that is within a binding Forecast unless such Purchase Order fails to comply with this clause 7.2.3

7.3 Capacity

ASM commits the required resources and capacities necessary in order to fulfill FOAMIX´s requirements for the Product(s) based on the then-current Forecast. If FOAMIX informs ASM that its demand for Products exceeds the amounts required pursuant to such Forecast and ASM might not be able to supply these volumes, ASM shall inform FOAMIX immediately. The Parties will then discuss in good faith how and by when ASM can cover the increased demand. ASM will use reasonable commercial efforts to supply FOAMIX with any increased demand of Products.

FOAMIX may submit Purchase Orders for quantities of Product in excess of the binding Forecast amounts (an "**Excess Purchase Order**"), and ASM shall use its reasonable commercial efforts to fill the excess amount of such Purchase Order and shall notify FOAMIX within five (5) Business Days after receipt of the applicable Purchase Order of the expected time, as determined in good faith by ASM (the "**Excess Fulfillment Time**") by which it expects to be able to fill such Excess Purchase Order. If ASM is not able to fill the Excess Purchase Order, this inability shall not constitute a "Supply Interruption" under Section 8.4 hereof.

8. DELIVERY AND LATE DELIVERY

8.1 Delivery and Shipment

ASM shall deliver the finished Products in the delivery quantities and at the confirmed delivery date as specified in the relevant Purchase Order. Each shipment of Product shall be delivered FCA Möhlin to the delivery address stated in the Purchase Order (lncoterms 2010). ASM shall provide (i) a delivery note detailing the packaging list, the Purchase Order number, the total number of finished Product per shipping box, the number of pallets and the number of shipping boxes per pallet, (ii) a certificate of analysis and the certificate of compliance certifying that Products have been Manufactured in conformity with the Specifications, CGMP, the applicable Quality Agreement, and (iii) any other documents as may be required by the relevant Governmental Authority of the Territory in which the Product will be sold, as previously defined by FOAMIX in due time.

No Product may be shipped under quarantine, unless expressly agreed to be shipped under quarantine by FOAMIX in writing.

8.2 Transfer of Products

FOAMIX shall own all rights, title and interest in the finished Products, and the risk of loss shall transfer to FOAMIX, once the finished Products are delivered to the common carrier selected by FOAMIX for shipment. FOAMIX shall pay all costs of shipping, storage, customs, duties, taxes, freight, insurance and other charges incurred by ASM in shipping the Product (collectively "**Transport Costs**"). FOAMIX shall reimburse ASM for any reasonable Transport Costs, without mark-up, actually incurred by ASM, and ASM shall, upon FOAMIX's request, provide written documentation supporting such costs.

8.3 DELAYED DELIVERY

ASM shall immediately, but in any event within three (3) Business Days of becoming aware thereof, notify FOAMIX of the occurrence of any event within or beyond its control that may result in a delay in fulfilling a Purchase Order, provided that the giving of such notice shall not otherwise excuse ASM's performance hereunder.

8.4 PRODUCT DISCONTINUANCE/SHORTAGE

If ASM (i) is unable to Manufacture the Product for FOAMIX according to the Specifications and terms of this Agreement, (ii) anticipates that it will become unable to produce and supply sufficient quantities of the Product to execute on time Purchase Orders or (iii) fails to deliver to FOAMIX on a timely basis the full amount of Product under any Purchase Order confirmed or deemed confirmed by ASM pursuant to clause 7.2.3) (in each case under clauses (i) - (iii), a "**Supply Interruption**"), ASM shall immediately, but in any event within five (5) calendar days of becoming aware of such situation notify FOAMIX. Such notification shall not prejudice FOAMIX's rights and remedies under this Agreement and applicable laws. ASM shall use reasonable commercial efforts to cure any Supply Interruption as soon as possible, and in any event within thirty (30) days from the Supply Interruption. Promptly following the event of a Supply Interruption, ASM shall prepare a plan to address any deficiencies or causes of such shortfall, provide a draft of the plan to FOAMIX for review and agreement, and shall implement all reasonable comments from FOAMIX as soon as possible. ASM shall provide weekly written status updates during the Supply Interruption on the progress towards remedy and cure of the Supply Interruption. If ASM fails to supply at least eighty percent (80%) of any Purchase Orders by the applicable delivery date in any three (3) consecutive calendar months or any three (3) calendar months within any five (5) consecutive rolling calendar month period and such failure is not due to the inability of FOAMIX to deliver the required amount of FOAMIX API Material or the unavailability of a necessary excipient or packaging component, a "**Supply Failure**" shall be deemed to have taken place. In the event of a Supply Failure, ASM shall provide FOAMIX with technology transfer and assistance as set forth in clause 24 below.

8.5 STANDARD FORMS

In ordering and delivering the Product, FOAMIX and ASM may use the standard forms as attached to this Agreement in Appendix 6, but nothing in those forms shall be construed to modify, amend or supplement the terms of this Agreement and, in the case of any conflict herewith, this Agreement shall control.

8.6 EMERGENCY PLANS

ASM shall at all times during the Term of this Agreement have business continuity plans, resources and personnel available to deal with contingency situations affecting the availability of such resources and personnel in its Facility to minimize the occurrence and impact of Supply Interruptions or Supply Failures.

9. PRICES

The price for finished Product that is Manufactured and supplied under this Agreement is set forth on Appendix 5 (the "**Price**"), as adjusted from time to time as set forth in clause 7.1.3. The Price shall include any and all costs for the Manufacture and supply of finished Product (other than the supply of FOAMIX API Material), including any costs related to quality control and assurance of the Products. ASM shall be responsible for submitting all payments to third parties for any Product Materials purchased from, or other products or services provided by, such third parties in connection with the Manufacture and supply of Products hereunder.

10. INVOICES AND PAYMENT

10.1 ASM shall invoice each supply of Products delivered to FOAMIX as specified in the relevant Purchase Order and pursuant to this Agreement. Invoices shall not be issued earlier than the delivery date and shall cite the Purchase Order number, batch number, Products code, quantity, unit price and total price.

10.2 Any amounts shall be paid by FOAMIX within 30 (thirty) days following the end of the month in which ASM's invoice was received. Payment shall be made by wire bank transfer in Swiss Francs (CHF) to an account designated by ASM. Payments received for any shipment of Product that is later rejected under the provisions of clause 17.6 hereof shall be credited by ASM to FOAMIX following the date on which the reason for the rejection of such Product is established.

10.3 Payment by FOAMIX shall not be deemed as acceptance of any Product.

11. CHANGES TO SPECIFICATIONS

11.1 Without the prior written consent of FOAMIX, ASM shall not modify or waive the Specifications, raw materials, production documents or any aspect of the Manufacturing Process for the Product nor alter the batch size of Products. ASM shall not manufacture the Product at any manufacturing facility other than the Facility.

11.2 FOAMIX may request changes to the Specifications in its discretion, provided that any amendment that proposes to change the Manufacturing Process of a Product shall not be effective until agreed upon by the Parties. If ASM proposes changes to the Specifications, it shall notify FOAMIX as early as practicable and the Parties shall agree on whether and when to implement such modification. The final decision on modifications of the Specifications remains solely at FOAMIX's discretion. To the extent that such modifications result in an increase or decrease in the cost of Manufacturing and/or packaging the Products, the Parties shall jointly examine and mutually agree upon the consequences thereof and shall make appropriate adjustments to the Product Price. ASM shall promptly notify FOAMIX of the date of implementation of any modification.

11.3 Each Party shall notify the other promptly of any request that it receives from a Governmental Authority to change, or which would have the effect of requiring a change to, the Specifications and/or Manufacturing Process. After written approval by FOAMIX, ASM shall promptly implement any such change in the Specifications and/or Manufacturing Process that may be requested by a Governmental Authority. Any additional costs incurred by ASM due to such change shall be borne by FOAMIX. ASM shall provide FOAMIX with the documentation required to evidence such changes and to support their approval by Governmental Authorities.

11.4 The cost of Product Material which becomes obsolete due to a change of Specifications induced by FOAMIX or a Governmental Authority shall be borne by FOAMIX, but only to the extent that such material cannot be used by ASM for other operations.

12. AUDITS AND INSPECTIONS

12.1 Pursuant to the Quality Agreement, ASM shall permit FOAMIX and any of their designated representatives every year to observe the Manufacturing of the Products, and audit on an annual basis that portion of the Facility where the Product is Manufactured to evaluate ASM's work practices, supporting systems, documents and records associated with the Products to assess ASM's compliance with applicable law, CGMP, the Quality Agreement and this Agreement. Such review shall be conducted only after reasonable advance notice, and during ordinary business hours and shall not unduly interfere with the normal business operations of ASM. Such audit shall be permitted to take place during Manufacturing of the Products. FOAMIX also has the right to inspect the Facility at any time during the Term of this Agreement if FOAMIX has reasonable cause to be concerned that the Facility or the Manufacture of the Products or storage of FOAMIX API Material is not in compliance with applicable law, CGMP or this Agreement. ASM shall be responsible for its own costs of such Audits or Inspections as set forth in this clause 12.1. Any costs for additional Audits or Inspections not contemplated by this clause 12.1 and requested by FOAMIX for the Products will be charged to FOAMIX.

12.2 ASM shall notify FOAMIX of its receipt of a notification by a Governmental Authority of any inquiry, communication or inspection by a Governmental Authority that directly or indirectly relates to the Manufacture of a Product, including of any facility used to warehouse the Product, and shall provide to FOAMIX all communications relating to such inspections within the timeframe, and as set forth, in the Quality Agreement. FOAMIX shall have the option of attending any such inspection that relates to the Products. Duplicate samples of the Product given to a Governmental Authority will be provided to FOAMIX. ASM shall furnish to FOAMIX, not later than five (5) Business Days prior to the time it provides the same to a Governmental Authority, one copy of the proposed response or explanation relating to any inquiry, communication or inspection set forth above. ASM shall allow FOAMIX to assist in any proposed response to a Governmental Authority that relates to the Products, including review of any written response made to such authority. ASM shall consider in good faith any comments proposed by FOAMIX on the proposed response. After the filing of a response, ASM shall notify FOAMIX, and promptly provide FOAMIX with copies, of any further contact with such Governmental Authority relating to the Product.

12.3 Physical Inventory Counts and Financial Reporting

ASM shall permit FOAMIX and any of their designated representatives to perform a physical inventory count of FOAMIX API Material or any other property to which FOAMIX has rights, title and interest in on at least an annual basis. Such physical inventory count shall be conducted only after reasonable advance notice, and during ordinary business hours and shall not unduly interfere with the normal business operations of ASM.

13. REGULATORY MATTERS AND QUALITY CONTROL

13.1 ASM shall secure and maintain in good order, at its sole cost and expense, all Governmental Authority Approvals, licenses and consents as are required to lawfully perform its obligations under this Agreement.

13.2 ASM shall maintain CGMP qualification of the Facility and shall make relevant qualification/validation reports available to FOAMIX for review. In case of new regulations having a significant economic impact upon the Manufacture of the Products, the Parties will discuss in good faith the allocation of costs resulting therefrom.

13.3 Product which does not comply with the Specifications and the warranties set forth herein shall not be delivered or invoiced by ASM. ASM will notify FOAMIX within one (1) Business Day at the latest after becoming aware of any Product's non-conformity with the Specifications. If FOAMIX confirms the non-conformity and requests in writing that the non-conforming Product or batch should be destroyed, then such Product shall be destroyed according to the applicable local laws and regulations, and ASM shall send FOAMIX proof of such destruction. The costs of such destruction shall only be borne by ASM if ASM, acting in good faith, accepts responsibility for the non-conforming Product. In case of disagreement or difficulties to determine the origin and/or responsibility for any non-conformity with the Specifications, FOAMIX and ASM will refer the matter to the respective independent testing laboratory set forth on Appendix 3 and accept the results of the assessment of the respective expert(s). The fees and expenses of such expert(s) shall be borne by the party ultimately determined to have incorrectly judged whether the Product was non-conforming.

13.4 FOAMIX shall obtain, maintain and own all filings necessary for approval by the applicable Governmental Authority of any and all filings for the commercial marketing or sales of Products in such country ("**Marketing Approval**"), along with satisfaction of any related applicable regulatory requirements. ASM shall use commercially reasonable efforts to assist FOAMIX in obtaining any Marketing Approvals related to the Product in any jurisdiction in the Territory. To enable FOAMIX to obtain and maintain Marketing Approval for the Products in the Territory as requested, ASM shall provide FOAMIX with all regulatory and technical information as may be requested by Governmental Authorities in any country in the Territory where Products are imported, marketed, sold or offered for sale. Where such information is confidential, ASM shall provide them directly to the requesting Governmental Authority. FOAMIX may use such information solely for the aforementioned purposes. FOAMIX shall pay for ASM's reasonable costs in providing such assistance, provided that such costs have been approved in writing by FOAMIX prior to their occurrence.

13.5 ASM shall provide FOAMIX with the appropriate technical support as FOAMIX may request to validate the Products in the frame of FOAMIX pharmaceutical production activities. The corresponding costs will be charged to FOAMIX.

14. PRODUCT COMPLAINTS AND ADVERSE EVENTS

FOAMIX and/or its Affiliates shall be responsible for the handling of all Product complaints and reports of adverse events, including those associated with Manufacture and shipment of the Products. ASM shall cooperate in the investigation by FOAMIX of all such Product complaints and reports of adverse events. Additional provisions relating to complaints and adverse events shall be addressed in the applicable Quality Agreement.

15. RECALL

15.1 Each Party shall keep the other Party informed of any notification or other material information which might affect the safety or efficacy of the Products and which might result in the Recall of a Product. ASM shall assist FOAMIX in its investigation to determine the cause and extent of the problem necessitating the Recall. Specific provisions relating to complaints, Recalls and corrective and preventative actions will be as stipulated in the Quality Agreement.

15.2 FOAMIX shall notify ASM of a decision to Recall the Product within one (1) day, as specified in the Quality Agreement.

15.3 FOAMIX shall be responsible for interacting with the competent Governmental Authority with respect to any Recall of the Products.

15.4 In the event of any Recall arising out of or resulting from ASM's failure to Manufacture the Product in accordance with the agreed Manufacturing Process as defined in the Specifications, in accordance with CGMP or the Quality Agreement, ASM shall:

15.4.1 at the election of FOAMIX, either (i) use reasonable commercial efforts to supply replacement Product within thirty (30) days of the date such Recall is initiated, without charge to FOAMIX, in an amount sufficient to replace the amount of recalled Product; or (ii) refund or credit to FOAMIX an amount equal to the price paid or to be paid by FOAMIX for the recalled Product; and

15.4.2 reimburse all transportation costs and export or import duties directly incurred by FOAMIX and not recovered by FOAMIX in respect of such recalled Product; and

15.4.3 in addition, reimburse FOAMIX (i) the reasonable and documented out-of-pocket expenses incurred by FOAMIX in connection with the Recall, and (ii) the purchase price paid by FOAMIX for the FOAMIX API Material used to Manufacture the recalled Product.

15.5 In the event of any Recall that does not arise out of or result from ASM's failure to Manufacture the Product in accordance with the agreed Manufacturing Process as defined in the Specifications, FOAMIX shall pay to ASM any unpaid purchase price of the Product recalled.

15.6 In the event of any Recall that arises out of or results from both (i) ASM's failure to Manufacture the Product in compliance with CGMP, the Specifications or the warranties agreed herein and (ii) a negligent act or omission of FOAMIX, the Parties shall negotiate in good faith an appropriate allocation of their out-of-pocket costs and expenses directly relating to such Recall.

16. INSURANCE

16.1 During the Term of this Agreement and for a period of three (3) years after its termination, both Parties shall maintain proper insurance from a reputable insurance company in order to cover their potential liability arising from this Agreement. This should include, without limitation, liability insurance (which shall include products liability), with limits of not less than CHF 2.000.000,00 (two million) per occurrence and CHF 5.000.000,00 (five million) per year. Each Party shall inform the other of a change of its insurance contract. Notwithstanding the above, the Parties agree that each Party may seek higher insurance limits and/or provide additional forms of insurance.

16.2 Upon request of the other party, each party shall provide the other party with updated certificates.

17. WARRANTIES

17.1 Due to the written Quality-Agreement signed jointly by the parties as attached in Appendix 2, the definition of responsibility is clearly defined. Intention of the Parties is to cover all probable scenarios relating to possible claims including corresponding costs.

17.2 FOAMIX shall be liable for failures caused by defects, delays and incompleteness of documents and/or FOAMIX API Materials provided or to be provided to ASM.

17.3 To the best knowledge of FOAMIX, the use of FOAMIX API Materials and FOAMIX Background IP in the Manufacture of Products in accordance with the Specifications and terms of this Agreement does not infringe on the Intellectual Property rights of a third party.

17.4 ASM represents and warrants to FOAMIX with respect to each delivery of Products hereunder that:

17.4.1 The Products are Manufactured in accordance with this Agreement (including the Quality Agreement), CGMP and the applicable laws and regulations;

17.4.2 The Products comply with the Specifications.

17.4.3 The Products are free and clear of any and all encumbrances , liens, or any other third party security claims.

17.4.4 ASM and all of its employees and personnel that shall be performing any work in connection with this Agreement shall have the appropriate training and skill necessary to perform their job functions.

17.4.5 To the best knowledge of ASM, ASM Background IP and ASM Developed IP does not infringe on the Intellectual Property rights of a third party.

17.5 Each party further represents and warrants as of the Effective Date of this Agreement, and agrees to ensure that throughout the Term of this Agreement:

17.5.1 It has received and is in current compliance with Governmental Approvals, licenses, consents and permits required to lawfully Manufacture, in the case of ASM, the Products and in the case of FOAMIX, to the best of its knowledge, the FOAMIX API Materials, pursuant to this Agreement. This includes all required Governmental Approvals and licenses to use the Facility under this Agreement. ASM represents and warrants that at the Effective Date it has not received any notice of adverse findings or similar letter from any Governmental Authority with respect to the Product or the Facility;

17.5.2 With respect to all filings to obtain marketing authorizations or Governmental Approvals by FOAMIX, the data and information in ASM's or FOAMIX' submissions are free from fraud or material falsity, that the Governmental Approvals will not be obtained through bribery or the payment of illegal gratuities, that the data and information in FOAMIX' and ASM's submissions are and shall be accurate and reliable for purposes of supporting approval of the submissions, and that the Governmental Approvals were and shall be obtained without illegal or unethical behaviour of any kind;

17.5.3 None of ASM or FOAMIX or any person or entity that was involved in the performance of ASM's obligations under this Agreement is under investigation by a Governmental Authority for debarment or is presently debarred by a Governmental Authority.

17.5.4 Neither party shall enter into any agreement or arrangement with any other entity that would prevent or in any way interfere with the other party's ability to perform its obligations hereunder.

17.5.5 It is a corporation, duly organized, validly existing and in good standing under the laws of its formation; it is duly qualified to do business in its respective jurisdiction of incorporation; it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and the execution of the Agreement by its representative whose signature is set forth at the end of this Agreement have been duly authorized by all necessary action on its part.

17.6 FOAMIX may reject any Product delivered under this Agreement that does not comply with the Specifications, CGMP, or the Manufacture Process(a "**Defective Product**") by giving written notice of such Defective Product to ASM within thirty (30) days after receipt of the Product. If FOAMIX accepts delivery of a Product but later determines that such Product delivered is a Defective Product and the nature of the defect could not have been discovered through the exercise of reasonable diligence within the thirty (30) day period, FOAMIX may revoke its acceptance by providing written notice of such revocation immediately after discovering such Defective Product. FOAMIX shall return any Defective Product to ASM at ASM's expense and ASM shall be required, at its sole expense, to:

17.6.1 rework, reprocess or recover any Defective Products if authorized by FOAMIX in writing; or

17.6.2 replace the Defective Products by Products of appropriate quality as soon as possible, subject to the availability of sufficient FOAMIX API Material.

17.7 If ASM and FOAMIX disagree as to whether any Product meets the Specifications, the Manufacture Process and/or warranties set forth in clause 17.1, the matter will be submitted to the reputed independent testing laboratory, acceptable to both Parties as set forth in Appendix 3, for analysis to determine whether the Product conformed or did not conform to the Specifications and the test results obtained from such laboratory shall be final and binding upon both Parties. The fees and expenses of such testing shall be borne by the Party ultimately determined to have incorrectly judged whether the Product met the said warranties. In case FOAMIX received a replacement shipment

17.7.1 and the laboratory decides that the first shipment failed to meet the Specifications due to a failure in the Manufacturing Process, FOAMIX shall pay only for the replacement shipment meeting the Specifications;

17.7.2 and the laboratory decides that the first shipment met the Specifications, then FOAMIX shall pay for both shipments meeting the Specifications as well as for the transportation costs for the replacement shipment.

17.8 ASM's representations and warranties set forth in clause 17.3 shall expire, with respect to each delivery of Products, fifteen (15) months after the date of delivery of the Product.

18. LEGAL COMPLIANCE

ASM will ensure that its officers, directors, employees and agents strictly comply with applicable laws that apply to the Manufacture as well as other applicable laws, including but not limited to the rules on prohibition of child labor, anti-corruption, anti-discrimination, environment protection and occupational health and safety.

19. INDEMNIFICATION

19.1 FOAMIX shall indemnify, defend and hold ASM, its officers, directors and employees harmless from and against all losses, damages (including regarding injuries to, or death of, any person, or injury to, or destruction of, property), liabilities and expenses (including reasonable attorneys' fees) and costs resulting from third-party claims, actions, orders or other pending or threatened proceedings ("**Losses**") to the extent arising out of: (i) FOAMIX's breach of any of its representations, warranties, or covenants hereunder, except in each case to the extent caused by the negligence, recklessness or willful misconduct of ASM or any ASM Indemnitee as defined in clause 19.3; (ii) the development or commercialization of the Product that meets the Specifications, (iii) the negligent acts, errors, omissions or the intentional misconduct of FOAMIX, its officers, directors, agents and employees; (iv) any failure of FOAMIX API Material supplied hereunder to conform to the FOAMIX API Material Specifications, as delivered to ASM.

19.2 ASM shall indemnify, defend and hold FOAMIX, its Affiliates and its and their respective officers, directors and employees harmless from and against Losses to the extent arising out of: (i) ASM's Manufacture or supply of the Product that fails to meet the Specifications, (ii) ASM's breach of any of its representations, warranties or covenants hereunder, except in each case to the extent caused by the negligence, recklessness or willful misconduct of FOAMIX or any FOAMIX Indemnitee as defined in clause 19.3; (iii) the negligent acts, errors or omissions or the willful or intentional misconduct of ASM, its officers, directors, agents and employees.

19.3 Promptly after the receipt by either ASM or FOAMIX of notice or otherwise becoming aware of (a) any claim or (b) the commencement of any lawsuit, action or proceeding which may give rise to a claim for indemnification hereunder, such Party (the "**Indemnitee**") will, if a claim with respect thereto is to be made against the Party obligated to provide indemnification pursuant to this clause (the "**Indemnitor**"), give such Indemnitor written notice of such claim or the commencement of such lawsuit, action or proceeding and shall permit the Indemnitor to assume, at its own expense, the defence of any such claim, lawsuit, action or proceeding. The Indemnitee shall permit the Indemnitor, at its discretion, to settle any such claim, lawsuit, action or proceeding, provided, however, that such settlement does not adversely affect the Indemnitee's rights hereunder or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights. No such claim, lawsuit, action or proceeding shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any Losses incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defence of any claim, lawsuit, action or proceeding covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by legal counsel of its own selection and expense in connection with any such proceeding.

19.4 If the Indemnitor shall not assume the defence of any such claim, lawsuit, action or proceeding, the Indemnitee may defend against such claim, lawsuit, action or proceeding in such manner as it may deem appropriate and the Indemnitee may settle such claim, lawsuit, action or proceeding on such terms as it may deem appropriate, and the Indemnitor shall promptly reimburse the Indemnitee for the amount of all Losses incurred by the Indemnitee in connection with the defence against or settlement of such claim, lawsuit, action or proceeding. If no settlement of such claim, lawsuit, action or proceeding is made, the Indemnitor shall promptly reimburse the Indemnitee for the amount of any Losses incurred by the Indemnitee in the defence against such proceeding.

19.5 This clause shall apply only to the extent permitted under applicable law and does not restrict or limit the liability of either Party towards each other. This Agreement does not limit the liability of the Parties under applicable laws for personal injuries, deaths and product liability and other mandatory liability imposed by applicable laws.

20. INTELLECTUAL PROPERTY

20.1 All Intellectual Property rights that are owned or controlled by a Party at the commencement of this Agreement shall remain under the ownership or control of such Party throughout the Term and thereafter (with respect to each Party, such Intellectual Property shall be deemed its "**Background IP**"). For clarity, all Intellectual Property related to the Products or the Manufacturing Process that exist as of the Effective Date shall be deemed Foamix Background IP, and FOAMIX shall retain and own and have the exclusive right, title and interest in and to all such Intellectual Property.

20.2 All new Intellectual Property that is generated, developed, conceived or reduced to practice under this Agreement, the Development Agreement or the Quality Agreement that (i) is related to the Products or the Manufacturing Process, including any modifications or improvements to any of the foregoing or (ii) that is otherwise based on, uses or incorporates any Foamix Confidential Information, shall be deemed "**FOAMIX Developed IP**", and shall be the exclusive property of FOAMIX.

20.3 Any new Intellectual Property that is generated, developed, conceived or reduced to practice under this Agreement or the Development Agreement by ASM that is not FOAMIX Developed IP shall be deemed "**ASM Developed IP**", and shall be the exclusive property of ASM. FOAMIX hereby grants to ASM a non-exclusive, non-transferable, irrevocable, perpetual, non-sublicensable, worldwide, royalty-free license during the Term of this Agreement, to use or have its designee use the FOAMIX Background IP and FOAMIX Developed IP to manufacture Products for FOAMIX and its Affiliates and sublicensees during the Term in accordance with this Agreement. ASM hereby grants to FOAMIX a non-exclusive, transferable, irrevocable, perpetual, sublicensable, worldwide, royalty-free license under the ASM Background IP and ASM Developed IP, in each case, to manufacture, sell, offer to sell, have made, have sold, import, export and otherwise distribute the Products, or any product or service based on or derived from the Products.

20.4 The Products may be advertised, promoted, marketed or sold, either separately or as part of other products, under any trademark, tradename, domain name, copyright or logo, whether registered or unregistered, selected by FOAMIX and its Affiliates in their sole discretion. ASM shall not adopt, use, apply for registration, register or own any such trademark, tradename, domain name, copyright or logo or any item confusingly similar thereto, in any country of the world, or take any action which, in FOAMIX's sole opinion, weakens or undermines such proprietary rights.

20.5 ASM shall promptly inform FOAMIX in writing of any new Intellectual Property (including FOAMIX Developed IP or ASM Developed IP), and all information, including know-how, in this respect shall be timely made available to FOAMIX in sufficient and full detail. ASM irrevocably assigns and undertakes to cause the personnel or any entity whatsoever including its Affiliates and subcontractors and their personnel to assign promptly all rights, title and interest worldwide in all FOAMIX Developed IP to FOAMIX without any additional consideration. ASM shall execute, and shall require its relevant personnel including those of its Affiliates and subcontractors to execute, any documents required to confirm FOAMIX's ownership of the FOAMIX Developed IP, and any documents required to apply for, maintain and enforce any patent or other intellectual property right in the FOAMIX Developed IP. Upon FOAMIX's request and reasonable expense, ASM will assist FOAMIX as may be necessary to apply for, maintain and enforce any patent or other intellectual property right in the FOAMIX Developed IP.

21. SUBCONTRACTING

21.1 ASM shall not, without the prior written consent of FOAMIX subcontract any of its obligations under this Agreement to any third party. The approved subcontractors are listed in Appendix 3.

21.2 ASM undertakes that its approved subcontractors shall be skilled and experienced contractors and shall comply with applicable laws and regulations. ASM undertakes that its subcontractors will carry out each of their activities for ASM so as to ensure that ASM complies with CGMP (where applicable). ASM undertakes that its subcontractors shall comply with the confidentiality and other obligations hereunder and that before allowing a subcontractor to begin work ASM shall enter into a written agreement with such subcontractor that obligates such subcontractor (and its personnel involved in the performance of such activities) to be bound by the terms and conditions of this Agreement in the same manner as they apply to ASM. ASM undertakes to fully pay its subcontractors all undisputed amounts when due. ASM agrees and will contractually ensure that FOAMIX and Governmental Authorities can conduct audits and inspections at the facilities of such subcontractors in accordance with clause 12.

21.3 ASM shall be fully responsible to FOAMIX for the acts or omissions of its subcontractors as if those acts or omissions had been carried out directly by ASM. The approval of any subcontracting under this Agreement shall not relieve or excuse ASM from its obligations to FOAMIX in respect of the proper performance of such obligations.

22. TERMINATION

22.1 Either Party shall have the right to terminate this Agreement at the end of the Initial Period or at the end of an Additional Period by providing the other party with no less than twelve (12) months prior written notice of such termination.

22.2 Notwithstanding the foregoing, a Party may terminate this Agreement with immediate effect:

(A) if any Party (the "**Defaulting Party**") breaches any material provision of this Agreement (other than breaches of any provision that are incapable of being cured) and remains in breach for thirty (30) days after receipt of written notice from the other Party (the "**Aggrieved Party**") requiring it to rectify the breach, the Aggrieved Party shall be entitled at its option and without prejudice to any other rights that it may have hereunder or at law:

22.2.1 to uphold this Agreement against the Defaulting Party and sue for specific performance of the Defaulting Party's obligations to it under this Agreement, with or without a claim for damages;

22.2.2 to uphold this Agreement and sue for damages; and/or

22.2.3 to terminate this Agreement and claim damages, in which case written notice of the termination shall be given to the Defaulting Party and the cancellation shall take effect on the giving of the notice.

(B) if the other Party is unable to pay its debts, becomes insolvent, makes an assignment for the benefit of creditors or commits any act amounting to a business failure, or if proceedings in bankruptcy or reorganization or for an appointment of a receiver or trustee for or over such Party's property are instituted by or against such Party in any court having jurisdiction thereof, and such proceedings are not vacated, set aside or stayed within ninety (90) days thereof, or if such Party attempts to enter into a general compromise of its liabilities.

23. EFFECTS OF TERMINATION

23.1 If this Agreement is terminated by ASM or by FOAMIX, then

23.1.1 at the request of FOAMIX, ASM shall be obligated to fill all outstanding Purchase Orders and FOAMIX shall be obligated to pay ASM the Price for Product, which is supplied in response to such outstanding Purchase Orders. Remaining Product Material purchased by ASM according to clause 7.1.2 and outstanding Purchase Orders will be invoiced to FOAMIX, and shall be payable within 30 days from the termination date.

23.1.2 FOAMIX shall have the right to order and purchase all of the Products projected for delivery in the next twelve (12) months of the current Annual Forecast. ASM shall deliver, and FOAMIX shall pay for the Products as ordered.

23.2 Upon expiration or termination of this Agreement for whatever reason,

23.2.1 each Party shall promptly return to the other Party all Confidential Information received from the other Party.

23.2.2 ASM shall promptly return to FOAMIX all FOAMIX API Materials in its possession or control.

23.2.3 ASM shall provide FOAMIX with all Product then manufactured or generated and all transferable work in progress.

23.2.4 ASM shall promptly transfer to FOAMIX all Foamix Developed IP in its possession or control.

24. TECHNOLOGY TRANSFER

Upon the request of FOAMIX in the event of a Supply Failure under clause 8.4 hereof, ASM will provide to FOAMIX commercially reasonable technology transfer of the then-current process and related know-how in accordance with the Specifications, for the commercial manufacture for the Products to a qualified third-party supplier (having the skills, trained personnel and certification), including related assistance to enable FOAMIX to manufacture such Product itself or through a third party manufacturer; provided that, such support and assistance shall in all respects be consistent with industry standards for such technology transfers. These efforts will be invoiced on an hourly basis to FOAMIX at ASM's then-existing hourly rates. Subject to the following sentence, FOAMIX shall be permitted to use a third party to Manufacture and supply the Products during a Supply Failure, and the exclusivity provisions in favour of ASM in clause 3.1 of this Agreement shall not apply.

Once the issue causing a Supply Failure is resolved, as mutually determined by the Parties acting in good faith, ASM will again be the primary supplier of the Products under this Agreement for the Term, Manufacturing at least 80% of FOAMIX's commercial needs for the Products in the Territory.

25. FORCE MAJEURE

25.1 Neither Party will be liable to the other for any default or delay in the performance of its obligations under this Agreement:

25.1.1 If and to the extent that such default or delay is caused by any act of God, epidemic, war or civil disturbance, or any other circumstance beyond its reasonable control (excluding any labor action (e. g. strikes) occurring at either Party or its Affiliates' premises); and

25.1.2 Provided that the non-performing Party is without fault in causing such default or delay, and such default or delay could not have been prevented by the non-performing Party, including through a work-around plan.

25.2 Following any circumstance of force majeure, the non-performing Party shall:

25.2.1 Notify the other Party within five days following the occurrence of such an event.

25.2.2 Use its best efforts to recommence performance; and

25.2.3 Co-operate with the other Party in implementing such contingency measures as the other Party may reasonably require.

25.3 The unaffected Party shall have the right to terminate this Agreement immediately upon written notice if an event of force majeure has not ceased after three (3) months from its start. For the avoidance of doubt, if there is a Supply Interruption following a force majeure, clause 8.4 shall apply.

26. CONFIDENTIALITY

26.1 From the Effective Date and for a period of ten (10) years, or for a perpetual time with respect to trade secrets, after this Agreement terminates, each Party or its Affiliate (the "receiving Party") shall:

26.1.1 keep the Confidential Information of the other Party or its Affiliate (the "disclosing Party") confidential;

26.1.2 not disclose the Confidential Information of the disclosing Party to any other person or entity other than with the prior written consent of the disclosing Party;

26.1.3 not use the Confidential Information of the disclosing Party for any purpose other than the performance of its obligations under this Agreement.

26.2 During the Term of this Agreement the receiving Party may disclose the Confidential Information of the disclosing Party to its Affiliates, and its or their employees, agents and representatives (including contractors, consultants and advisors) (each, a "Representative') to the extent that it is necessary for the purposes of this Agreement. The Party disclosing the information to its Representatives shall ensure that each Representative is made aware of and complies with the receiving Party's obligations of confidentiality under this Agreement.

26.3 The obligations imposed by this clause upon the receiving Party shall not apply to any Confidential Information of the disclosing Party which:

26.3.1 is in or comes into the public domain other than as a result of a breach of this Agreement; or

26.3.2 is known to the receiving Party prior to obtaining the same from the disclosing Party, as demonstrated by written records;

26.3.3 is obtained by the receiving Party from a third party who is not obligated to keep the information confidential; or

26.3.4 is required to be disclosed by applicable law or a valid order of a court, provided that the receiving Party promptly notifies the disclosing Party of the requirement of such disclosure, takes reasonable and lawful actions to avoid or minimize the degree of such disclosure and to have confidential treatment accorded to any Confidential Information disclosed, and cooperates fully with the disclosing Party in connection with the disclosing Party's efforts to apply for a protective order or take other appropriate action to restrict disclosure of the Confidential Information.

26.4 Notwithstanding the foregoing provisions of this clause, FOAMIX shall also be entitled to submit and disclose to any Governmental Authority confidential documents and information of ASM in accordance with clause 13.4. FOAMIX shall also be entitled to disclose the terms of this Agreement with sufficiently redacted commercial terms to a third party considering or providing financing to FOAMIX or in connection with an M&A transaction involving FOAMIX; provided that any such third party agrees to be bound by confidentiality restrictions that are at least as restrictive as those contained herein.

27. GOVERNING LAW AND PLACE OF JURISDICTION

27.1 This Agreement shall be governed by and enforced in accordance with the laws of Switzerland.

27.2 Any dispute, controversy or claim arising out of, or in relation to, this contract that was not resolved pursuant to the dispute resolution procedure set forth in this Agreement (including pursuant to clause 17.7) or clause 27.3 below, including the validity, invalidity, breach, or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers' Arbitration Institution in force on the date on which the Notice of Arbitration is submitted in accordance with these Rules.

The number of arbitrators shall be one or three; the seat of the arbitration shall be Zürich, Switzerland. The arbitral proceedings shall be conducted in English.

27.3 In the event any dispute or controversy arises, the Parties will first present the matter to a senior executive (one who reports to the Chief Executive Officer) of each of ASM and FOAMIX for resolution. If the senior executives cannot resolve the situation within twenty one (21) calendar days, then either Party may, except as otherwise set forth in clause 17.7 of this Agreement, submit the dispute to binding arbitration or initiate legal proceeding. This dispute resolution process does not prevent a Party from seeking urgent or interim relief before the courts of competent jurisdiction.

28. NOTICES AND LEGAL PROCESS

28.1 Each Party chooses as its address for all purposes under this Agreement, whether for serving any court process or documents, giving any notice, or making any other communications of whatsoever nature and for any other purpose arising from this Agreement, as follows:

FOAMIX:
Foamix Pharmaceuticals Ltd.
Attn: Head of Pharmaceutical Development
2 Holzman Street
Rehovot Science Park
Rehovot
Israel
Tel.: +972 8 931 6233
Email: Russell.elliott@foamix.com

And

General Counsel
c/o Foamix Pharmaceuticals Inc.
520 U.S. Highway 22, Suite 204
Bridgewater, NJ
USA
Tel.: +18007757936
Email: Mutya.harsch@foamix.com

Manufacturer:
ASM Aerosol-Service AG
Attn.: CEO
Industriestrasse 11
4313 Möhlin
Switzerland
Tel.: +41 61 855 67 67
Email: info@aerosol-service.com

Any Party may by notice to the other Party change its chosen address to another physical address.

28.2 Any notice required or permitted under this Agreement shall be valid and effective only if in writing. Notwithstanding anything to the contrary herein, a written notice actually received by a Party, including a notice sent by fax, shall be adequate for the purposes of this Agreement notwithstanding that it was not sent or delivered to the chosen address.

29. INTERPRETATION

29.1 Clause and paragraph headings are for purposes of reference only and shall not be used in interpretation.

29.2 Unless the context clearly indicates a contrary intention, any word connoting: any gender includes all genders; the singular includes the plural and vice versa; persons includes artificial persons and vice versa; insolvency includes provisional or final sequestration, liquidation or judicial management.

29.3 The rule of interpretation that a written agreement shall be interpreted against the Party responsible for the drafting or preparation of that agreement shall not apply.

29.4 If any provision in a definition is a substantive provision conferring rights or imposing obligations on any Party, notwithstanding that it is only in the definition clause, effect shall be given to it as if it were a substantive provision in the body of the Agreement.

29.5 In the event of any conflict or contradiction between this Agreement and an Appendix, the provisions of this Agreement shall control, except with respect to conflicts or contradictions principally of a quality or technical nature, in which case the applicable Quality Agreement shall control.

30. LIMITATION OF LIABILITY

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, SUBSEQUENT, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE ENTIRE LIABILITY OF EITHER PARTY SHALL BE LIMITED TO THE GREATER OF (I) THE ANNUAL AGGREGATE PURCHASE ORDER VOLUME OR (II) ONE MILLION SWISS FRANCS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 19, OR DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, OR FOR BREACHES BY A PARTY OF ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN CLAUSE 26.

31. GENERAL AND MISCELLANEOUS

31.1 Entire Agreement

This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and shall supersede all previous communications, representations or undertakings, either verbal or written, between the Parties relating to the subject matter hereof; provided that, the Development Agreement shall remain in full force and effect, except that in the event of a conflict between the terms of this Agreement and the terms of the Development Agreement, the terms of this Agreement shall control. No general terms and conditions of either Party apply to their collaboration agreed hereunder unless agreed and signed by both Parties.

31.2 Written Form Requirement

No addition to, variation of, or agreed cancellation of, this Agreement or this written-form-clause shall be effective unless in writing and signed by both Parties.

31.3 Waivers

No relaxation or indulgence which any Party may grant to any other shall constitute a waiver of the rights of that Party and shall not preclude that Party from exercising any rights which may have arisen in the past or which might arise in future.

31.4 Survival of Obligations

Any provision of this Agreement which contemplates performance or observance subsequent to any termination of this Agreement shall survive any termination of this Agreement and continue in full force and effect, including without limitation, clauses 5 through 17 (inclusive), 19, 20, 23, 26 through 31 (inclusive).

31.5 Approvals And Consents

An approval or consent given by a Party under this Agreement shall only be valid if in writing and shall not relieve the other Party from responsibility for complying with the requirements of this Agreement nor shall it be construed as a waiver of any rights under this Agreement except as and to the extent otherwise expressly provided in such approval or consent, or elsewhere in this Agreement.

31.6 Independent Contractors

Nothing contained in this Agreement shall be construed to constitute either Party as the agent or representative of the other Party, nor constitute the Parties together as partners or joint ventures. Each Party represents itself and acts on its own behalf. Neither Party shall be responsible for the acts or omissions of the other Party, nor have the authority to speak for, act on behalf of, or obligate the other Party in any way, without the prior written consent of the other Party.

31.7 Counterparts

This Agreement may be executed in any number of counterparts, each of which when executed shall be an original, but all the counterparts together shall constitute one document.

31.8 Severability

If any provision of this Agreement is held to be void, invalid or unenforceable under applicable law, the rest of the Agreement shall remain in full force and effect. In lieu of the illegal, invalid or unenforceable provision, the Parties will agree on a legal, valid and enforceable provision which comes as close as possible to the original legal and commercial intent of the provision that needs to be replaced.

31.9 Assignment

Any attempted assignment of the rights or delegation of the obligations under this Agreement shall be void without the prior written consent of the nonassigning or nondelegating Party; provided, however, that either Party may assign its rights or delegate its obligations under this Agreement without such consent (i) to an Affiliate of such Party or (ii) to a third party acquiring or licensing all or substantially all of FOAMIX's assets or a Product or in the event of a change of control, other than to a third party that is a direct competitor of the nonassigning or nondelegating Party,of such Party. In the case of any permitted assignment or transfer of or under this Agreement: (x) this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assigns of the Parties hereto; (y) any successor to a Party shall agree in writing to be so bound under the terms of this Agreement; and (z) shall promptly send a copy of such writing to the other Party.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date set forth above.

FOAMIX PHARMACEUTICALS LTD.

By: /s/ David T. Domzalski
Name: David T. Domzalski
Title: Chief Executive Officer

FOAMIX PHARMACEUTICALS LTD.

By: /s/ Mutya Harsch
Name: Mutya Harsch
Title: General Counsel

ASM AEROSOL-SERVICE AG

By: /s/ Peter Bernauer
Name: Peter Bernauer
Title: Chief Executive Officer

ASM AEROSOL-SERVICE AG

By: /s/ Geir Legreid
Name: Geir Legreid
Title: Project Manager

Exhibit 21.1

Foamix Pharmaceuticals Ltd.

The following is a list of subsidiaries of Foamix Pharmaceutical Ltd. as of December 31, 2019:

SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Foamix Pharmaceutical Inc.	Delaware

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, David Domzalski, certify that:

1. I have reviewed this report on Form 10-K of Foamix Pharmaceuticals Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2020

By: /s/ David Domzalski
David Domzalski
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Ilan Hadar, certify that:

1. I have reviewed this report on Form 10-K of Foamix Pharmaceuticals Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2020

By: /s/ Ilan Hadar
Ilan Hadar
Chief Financial Officer and Country Manager

Exhibit 32.1

CERTIFICATION OF CEO PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Foamix Pharmaceuticals Ltd. (the "**Company**") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), David Domzalski, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

By: /s/ David Domzalski
David Domzalski
Chief Executive Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 32.2

CERTIFICATION OF CFO PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Foamix Pharmaceuticals Ltd. (the "**Company**") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), Ilan Hadar, as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

By: /s/ Ilan Hadar
Ilan Hadar
Chief Financial Officer and Country Manager

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.