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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 21, 2019

FOAMIX PHARMACEUTICALS LTD.

(Exact name of registrant as specified in its charter)

Israel
(State or other jurisdiction of incorporation)

001-36621
(Commission File Number)

N/A
(IRS Employer Identification No.)

**2 Holzman Street,
Weizmann Science Park
Rehovot, Israel**
(Address of principal executive offices)

7670402
(Zip Code)

+972-8-9316233
(Registrant's telephone number, including area code)
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Ticker symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value NIS 0.16 per share	FOMX	Nasdaq Global Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 1.01 Entry into a Material Definitive Agreement.

On October 21, 2019 (the “Effective Date”), Foamix Pharmaceuticals Ltd. (“Foamix” or the “Company”) entered into a Contract Manufacturing and Supply Agreement (the “Agreement”) with ASM Aerosol-Service AG (“ASM”) pursuant to which ASM will exclusively manufacture and supply the Company’s recently approved AMZEEQ™ (minocycline) topical foam, 4%, and its product candidate, FMX103 (minocycline) topical foam, 1.5% (collectively, the “Products”), for a specified price per can of product. The Agreement has an initial term of four years (the “Initial Period”) and will automatically renew for further periods of two years thereafter (an “Additional Period,” and together with the Initial Period, the “Term”) unless terminated pursuant to the terms of the Agreement.

Pursuant to the Agreement, ASM has agreed to manufacture and supply all of Foamix’s commercial needs for the Products on an exclusive basis for a period of four years following the Effective Date, subject to certain exceptions. During this four-year period, Foamix is, directly or through a third-party contractor, permitted to engage in manufacturing activities in order to qualify a secondary supplier to manufacture and supply the Products following the exclusivity period or in the event that ASM is unable to supply the Products, subject to the conditions set forth in the Agreement. ASM will procure the raw materials, other than the active pharmaceutical ingredient (which will be provided to ASM at no cost by Foamix), necessary for the manufacturing of the Products. The Products will be supplied pursuant to purchase orders which Foamix may deliver from time to time. In addition, Foamix will be required to deliver a rolling forecast of its expected commercial orders, a portion of which will be considered a binding purchase order. Foamix is not required to purchase a minimum amount of the Products under the Agreement. In addition, ASM will not be permitted to manufacture or supply to a third party any topical product containing minocycline or minocycline hydrochloride during the Term and for two years after the termination or expiration of the Agreement.

Either party may terminate the Agreement at the end of the Initial Period or at the end of an Additional Period by providing the other party a minimum of 12-months’ notice of such termination. Furthermore, either party may terminate the Agreement with immediate effect upon the bankruptcy or material breach (after a 30-day cure period) of the other party.

The Agreement also contains customary representations and warranties, as well as provisions relating to payment, delivery and shipment, regulatory matters and quality control, indemnification, recall, confidentiality and other matters.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2019. The Company intends to redact certain portions of the Agreement for confidentiality purposes.

Item 7.01 Regulation FD Disclosure

In connection with the foregoing, on October 23, 2019, Foamix issued a press release entitled “Foamix Enters into Manufacturing and Supply Agreement for AMZEEQ™ and FMX103.” A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 7.01 and Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release entitled “Foamix Enters into Manufacturing and Supply Agreement for AMZEEQ™ and FMX103,” dated October 23, 2019.

SIGNATURES

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 hereunto duly authorized.

Date: October 23, 2019

FOAMIX PHARMACEUTICALS LTD.

By: /s/ Mutya Harsch
Mutya Harsch
Chief Legal Officer



Foamix Enters Into Manufacturing and Supply Agreement For AMZEEQ™ and FMX103

Triggers availability of non-dilutive capital under existing credit agreement with Perceptive and OrbiMed

REHOVOT, Israel and BRIDGEWATER, N.J., October 23, 2019 – Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) (“Foamix” or the “Company”), a specialty pharmaceutical company, today announced that it has entered into a long term contract manufacturing and supply agreement with ASM Aerosol-Service (“ASM”) for the Company’s recently approved AMZEEQ™ (minocycline) topical foam, 4% for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older and for its product candidate FMX103 (minocycline) topical foam, 1.5% for the potential treatment of moderate to severe papulopustular rosacea in adults. Under the terms of the agreement, ASM will manufacture and supply AMZEEQ and FMX103 at its facility in Möhlin, Switzerland.

“This agreement represents another milestone in our overall strategy to bring AMZEEQ to market in January 2020 and to commercialize FMX103 when and if approved by the FDA,” said David Domzalski, Chief Executive Officer of Foamix. “Entering into a manufacturing contract with ASM is a critical step in securing our supply chain, which we believe will ensure the availability of supply once we launch AMZEEQ and, if approved, FMX103.”

With the receipt of FDA approval of AMZEEQ (formerly known as FMX101) and entry into the contract manufacturing and supply agreement with ASM, the Company now has access to up to an additional \$20 million of financing under its existing credit agreement with Perceptive and OrbiMed to fund the commercial launches of AMZEEQ and, pending FDA approval, FMX103.

About Foamix Pharmaceuticals

Foamix is a specialty pharmaceutical company working to solve some of today’s most difficult therapeutic challenges in dermatology and beyond.

With expertise in topical medicine innovation as a springboard, the Company is working to develop and commercialize solutions that were long thought impossible, including the world’s first topical minocycline, AMZEEQ. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in AMZEEQ and in the Company’s products currently in development: FMX103 for the potential treatment of moderate to severe papulopustular rosacea and FCD105 for the potential treatment of moderate to severe acne.

Foamix is a different type of specialty pharmaceutical company by design, driven to see the solutions, overcome barriers in all aspects of business, and reimagine what’s possible for conditions with high unmet needs.

Foamix uses its website as a channel to distribute information about Foamix and its product candidates from time to time. Foamix may use its website to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Foamix’s website in addition to following its press releases, filings with the Securities and Exchange Commission, public conference calls, and webcasts. For more information, visit www.foamix.com.

Cautionary Note Regarding Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this press release which are not historical facts are forward-looking statements, including, but not limited to, statements regarding the future expectations, plans and prospects for Foamix; anticipated manufacturing and commercialization plans of AMZEEQ and projected date to be available for prescription; future development and manufacturing plans regarding FMX103 and the potential approval of FMX103 by the FDA. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, determination by the FDA that results from clinical trials are not sufficient to support registration or marketing approval of the Company's product candidates; the risk that the Company's product candidates will not be successfully developed, approved or commercialized; unexpected delays in clinical trials or announcement of results; the Company's ability to effectively and timely conduct clinical trials in light of excess costs or unfavorable results of clinical trials; risks that the Company's intellectual property rights, such as patents, may fail to provide adequate protection, may be challenged and one or more claims may be revoked or interpreted narrowly or will not be infringed; risks that any of the Company's patents may be held to be narrowed, invalid or unenforceable or one or more of the Company's patent applications may not be granted and potential competitors may also seek to design around the Company's granted patents or patent applications; delays or denial in the U.S. regulatory approval process; additional competition in the acne and dermatology markets; risks associated with denial of reimbursement by third party payors; the Company's ability to raise additional capital; risks associated with third-party manufacturers and suppliers; and the Company's ability to recruit and retain key employees. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. Although the Company believes these forward-looking statements are reasonable, they speak only as of the date of this release and the Company undertakes no obligation to update this information to reflect subsequent events or circumstances, except as otherwise required by law. Given these risks and uncertainties, you should not rely upon forward-looking statements as predictions of future events.

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