
**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): January 14, 2020

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 7.01 Regulation FD Disclosure.

On January 14, 2020, Foamix Pharmaceuticals Ltd. (the “Company”) issued a press release entitled “Foamix Announces AMZEEQ™ (minocycline) Achievement of Preferred Status on Express Scripts National Preferred Formulary, One of the Largest Commercial Formularies in the U.S.” 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>
<u>99.1</u>	<u>Press release entitled “Foamix Announces AMZEEQ™ (minocycline) Achievement of Preferred Status on Express Scripts National Preferred Formulary, One of the Largest Commercial Formularies in the U.S.,” dated January 14, 2020.</u>

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: January 14, 2020

FOAMIX PHARMACEUTICALS LTD.

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



**Foamix Announces AMZEEQ™ (minocycline)
Achievement of Preferred Status on Express Scripts National Preferred
Formulary, One of the Largest Commercial Formularies in the U.S.**

Preferred Coverage Effective Immediately on Express Scripts National Preferred, Flex, and Basic Formularies

AMZEEQ is the First FDA Approved Topical Form of Minocycline for the Treatment of Moderate to Severe Acne

REHOVOT, Israel and BRIDGEWATER, N.J., January 14, 2020 -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a specialty pharmaceutical company, today announced a coverage update for its novel AMZEEQ™ (minocycline) topical foam, 4%. AMZEEQ is indicated 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. AMZEEQ is the first topical minocycline to be approved by the U.S. Food and Drug Administration (FDA) for any condition.

The Company announced that AMZEEQ has achieved preferred coverage effective immediately on the Express Scripts National Preferred, Flex, and Basic commercial formularies. As a preferred medication, AMZEEQ will be available at a lower out-of-pocket cost to the represented Express Scripts plan members compared to acne medications which are non-preferred or excluded.

The Company recently announced that the annual list price of AMZEEQ is \$485 per 30-gram canister, a lower per unit cost than that of current brand leaders within the acne prescription market.

"As one of the largest pharmacy benefit managers in the U.S., Express Scripts' decision to include AMZEEQ as a preferred agent on its national formularies is a significant step toward ensuring access to AMZEEQ for millions of moderate to severe acne patients," said David Domzalski, Chief Executive Officer of Foamix. "We believe our pricing and overall access strategy prioritizes patients and their healthcare providers by providing a novel, first-of-its-kind acne treatment at pricing designed to help reduce barriers to treatment with AMZEEQ."

Minocycline, a broad-spectrum antibiotic known for its efficacy in treating moderate to severe acne, has not previously been available as a topical treatment due to its instability in traditional topical formulations. In AMZEEQ, Foamix has leveraged its proprietary Molecule Stabilizing Technology (MST™) platform to deliver minocycline in a foam-based vehicle that maintains the stability of the active ingredient while delivering it directly on the skin.

AMZEEQ was approved by the U.S. Food and Drug Administration in October 2019. The Company has previously announced that the product is available in pharmacies nationwide as of January 13th.

About AMZEEQ™

INDICATIONS AND USAGE

AMZEEQ™ (minocycline) topical foam, 4% is indicated 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.

Limitations of Use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, AMZEEQ should be used only as indicated.

IMPORTANT SAFETY INFORMATION

Contraindications

- Persons who have shown hypersensitivity to any of the tetracyclines or any other ingredient in AMZEEQ.

Warnings and Precautions

Flammability: The propellant in AMZEEQ is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application.

AMZEEQ is a topical foam. While systemic absorption of AMZEEQ is low, and serious adverse reactions were not seen in clinical studies, the following adverse reactions associated with oral minocycline should be considered:

- *Teratogenic effects, inhibition of bone growth, & permanent tooth discoloration: Use during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.*
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- *Clostridium difficile* associated diarrhea (CDAD): If CDAD occurs, discontinue AMZEEQ.
- *Hepatotoxicity & metabolic effects*: If renal impairment exists or if liver injury suspected, discontinue AMZEEQ.
- *Central nervous system effects*: Patients experiencing light-headedness, dizziness, or vertigo should be cautioned about driving vehicles or operating heavy machinery.
- *Intracranial hypertension*: Clinical manifestations include headache, blurred vision, diplopia, and vision loss. Discontinue AMZEEQ immediately if symptoms occur.
- *Autoimmune syndromes*: Symptoms may be manifested by fever, rash, arthralgia, and malaise. Discontinue AMZEEQ immediately if symptoms occur.
- *Photosensitivity*: Patients should minimize or avoid exposure to natural or artificial sunlight while using AMZEEQ. Advise patients to discontinue treatment with AMZEEQ at the first evidence of sunburn.
- *Hypersensitivity reactions*: Discontinue AMZEEQ immediately if symptoms of anaphylaxis, serious skin reactions, erythema multiforme, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome occur.
- *Tissue Hyperpigmentation*: Discoloration of organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae, and heart valves.
- *Superinfection*: Overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue AMZEEQ and institute appropriate therapy.

Adverse Reactions

- The most common adverse reaction reported during clinical trials of AMZEEQ was headache.

To report SUSPECTED ADVERSE REACTIONS, contact Foamix Pharmaceuticals Inc. at **1-844-375-3673** or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch

Please see full Prescribing Information.

About Acne

Acne is a chronic, inflammatory skin condition that affects the skin's sebaceous glands and hair follicles. It is characterized by both inflammatory lesions (papules and pustules) and non-inflammatory lesions (open and closed comedones) affecting primarily the face and truncal areas of the body. Acne affects approximately 40 to 50 million people in the U.S. alone, of whom approximately 10 million have moderate to severe disease that may impact self-esteem and quality of life. For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals, particularly women, can experience acne much later in life.

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. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in Amzeeq, the world's first topical minocycline, and in the Company's other 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 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.

Forward-Looking Statements

This 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 and the commercialization plans of AMZEEQ, including the pricing, availability and healthcare and patient adoption of AMZEEQ to treat moderate to severe acne vulgaris in adults and pediatric patients. Forward-looking statements are based on Foamix's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors including, but not limited to, adverse events associated with AMZEEQ; the outcome of pricing, coverage and reimbursement negotiations with third party payors for AMZEEQ or any other products or product candidates that Foamix may commercialize in the future; whether, and to what extent, third party payors impose additional requirements before approving AMZEEQ prescription reimbursement; the eligible patient base and commercial potential of AMZEEQ or any of Foamix's other product or product candidates; additional competition in the acne and dermatology markets; inability to raise additional capital; Foamix's ability to recruit and retain key employees and its ability to stay in compliance with applicable laws, rules and regulations. Foamix discusses many of these risks in greater detail in its periodic filings with the SEC, including under the heading "Risk Factors" in its most recent annual report and subsequent quarterly reports. Although Foamix believes these forward-looking statements are reasonable, they speak only as of the date of this announcement and Foamix undertakes no obligation to update publicly such forward-looking statements 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.

Corporate Contact:

Ilan Hadar, CFO
Foamix Pharmaceuticals Ltd.
+972-8-9316233
ilan.hadar@foamixpharma.com

Media Relations:

Rebecca Schechner
Zeno Group
312-586-3429, x5632
rebecca.schechner@zenogroup.com

U.S. Investor Relations:

Joyce Allaire
LifeSci Advisors, LLC
646-889-1200
jallaire@lifesciadvisors.com



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