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 9, 2020

FOAMIX PHARMACEUTICALS LTD.
(Exact name of registrant as specified in its charter)

Israel	**001-36621**	**N/A**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Holzman Street, **Weizmann Science Park** **Rehovot, Israel**	**7670402**
(Address of principal executive offices)	(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 8.01 Other Events.

On January 9, 2020, Foamix Pharmaceuticals Ltd. issued a press release announcing that its novel AMZEEQ™ (minocycline) topical foam, 4% will be available on January 13, 2020 by prescription 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. A copy of the press release is attached as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release entitled "Foamix Announces AMZEEQ™ (minocycline) Topical Foam Available in Pharmacies Nationwide on January 13th for the Treatment of Moderate to Severe Acne," dated January 9, 2020.

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 9, 2020

FOAMIX PHARMACEUTICALS LTD.

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

Exhibit 99.1

Foamix Announces AMZEEQ™ (minocycline) Topical Foam Available in Pharmacies Nationwide on January 13th for the Treatment of Moderate to Severe Acne

AMZEEQ is the First FDA Approved Topical Form of Minocycline and the Company's First Commercial Launch

AMZEEQ Offers Efficacy with Low Systemic Absorption

List price of $485 Competitive Against Current Acne Market Leaders

REHOVOT, Israel and BRIDGEWATER, N.J., January 9, 2020 -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a specialty pharmaceutical company, today announced that its novel AMZEEQ™ (minocycline) topical foam, 4% will be available on January 13, 2020 by prescription 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. Approved by the U.S. Food and Drug Administration (FDA) in October 2019, AMZEEQ is the first topical minocycline to be FDA approved for any condition and represents the company's first commercial product launch. This new once-daily therapy will be available in retail, community and specialty pharmacies nationwide.

The Company also announced that the annual list price of AMZEEQ will be $485 per 30-gram canister. This is a lower price per unit than that of current brand leaders in the acne prescription market, setting AMZEEQ apart in terms of its pricing approach.

Foamix employed a team of experts to develop the Company's approach for engaging commercial insurers to offer the broadest possible access to AMZEEQ for patients and healthcare professionals. The Company will provide copay card assistance for eligible commercially insured patients. An electronic benefit verification tool is also available through the product website, AMZEEQ.com, to assist healthcare professionals and patients to understand their likely insurance coverage and out-of-pocket costs.

Foamix has also developed a multi-channel tactical marketing plan to reach customers, including a sales force deployment to more than 6,000 acne-treating providers with product samples. Foamix will broadcast a promotional speaker program for relevant health care professionals ("HCPs") nationally on February 13, 2020 to share AMZEEQ product and prescribing information. In addition, Foamix is deploying a broad range of digital consumer outreach tactics, including product information and a unique unboxing-style "how to use" video designed to be easily understood by an adolescent patient population and based on AMZEEQ's instructions for use.

“Moderate to severe acne is a challenging and burdensome condition of many sufferers. AMZEEQ is now positioned to become an important tool in managing this condition,” said David Domzalski, Chief Executive Officer of Foamix. “We recognize that providers and acne sufferers have been seeking alternatives in acne treatment, and I’m very proud of the program we’ve designed to provide broad awareness and availability of AMZEEQ for physicians and patients.”

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. With the development of AMZEEQ, Foamix has leveraged its proprietary Molecule Stabilizing Technology (MST™) platform to conveniently and effectively deliver minocycline in a foam-based vehicle that maintains the stability of the active ingredient while delivering it directly on the skin.

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.
- *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 oil 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; anticipated commercialization plans of AMZEEQ including the potential for AMZEEQ to treat moderate to severe acne vulgaris in adults and pediatric patients and projected date to be available for prescription; and expectations regarding the size of eligible patient population for AMZEEQ and the anticipated patient benefit. 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.

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