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): August 5, 2019

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 August 5, 2019, Foamix Pharmaceuticals Ltd., issued a press release entitled "Foamix Submits New Drug Application to U.S. FDA for FMX 103 for the Treatment of Moderate-to-Severe Papulopustular Rosacea." 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 Submits New Drug Application to U.S. FDA for FMX 103 for the Treatment of Moderate-to-Severe Papulopustular Rosacea," dated August 5, 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: August 5, 2019

FOAMIX PHARMACEUTICALS LTD.

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

Exhibit 99.1

Foamix Submits New Drug Application to U.S. FDA for FMX103 for the Treatment of Moderate-to-Severe Papulopustular Rosacea

Rehovot, Israel, and Bridgewater, NJ – August 5th , 2019 – Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical therapies to address unmet needs in dermatology, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for FMX103 for the treatment of moderate-to-severe papulopustular rosacea in patients 18 years of age and older.

Rosacea is a common skin condition that causes redness and visible blood vessels in the face. It may also produce small, red, pus-filled bumps. These signs and symptoms may flare up for a period of weeks to months and then diminish for a while. Rosacea can be mistaken for acne, an allergic reaction or other skin problems. There are approximately 16 million U.S. rosacea sufferers (source: Aimee Two, MD, *et al*, JAAD, Volume 72, Issue 5, May 2015), a large percentage of whom (85% 30 years of age and older) suffer multiple comorbidities and experience sensitivity to current treatment options.

“It can be challenging for patients with papulopustular rosacea to find therapies that provide meaningful symptom relief and are also well tolerated when applied to their skin,” said David Domzalski, Chief Executive Officer. “Building on the impressive Phase 3 FMX103 topline results announced in November last year, we are excited to have reached this NDA submission milestone earlier than previously anticipated.”

The NDA submission is supported by the previously communicated results from two Phase 3 clinical trials, FX2016-11 and FX2016-12. In these trials, FMX103 achieved both co-primary endpoints, demonstrating statistically significant improvements in inflammatory lesion count and Investigator Global Assessment (IGA) treatment success. In both trials, and in the long-term safety extension study FX2016-13, the safety profile of FMX103 was shown to be generally favorable and consistent throughout the clinical development program. The NDA submission also incorporates information on chemistry manufacturing and controls, and data from non-clinical toxicology studies.

“Our goal with developing FMX103 is to provide patients with an efficacious and well-tolerated treatment in a convenient topical foam formulation,” stated Iain A. Stuart, Ph.D., Chief Scientific Officer. “This submission for FMX103, which is the second NDA submitted by Foamix within the past 8 months, underscores both the potential of our late stage portfolio in dermatology as well as the strong execution capabilities of our R&D and regulatory teams.”

About Foamix Pharmaceuticals
Foamix is a specialty pharmaceutical company focused on the development and commercialization of proprietary, innovative and differentiated topical therapies to treat dermatological diseases. Our leading clinical stage product candidates are FMX101 and FCD105 which are intended for the treatment of moderate-to-severe acne vulgaris and FMX103 which is intended for the treatment of papulopustular rosacea. We continue to pursue research & development of our proprietary, innovative topical delivery technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies including LEO Pharma A/S and others.

Foamix uses its website (www.Foamix.com) 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 & Exchange Commission, public conference calls, and webcasts.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the future development plans of FMX103. All statements other than statements of historical facts are forward-looking statements. 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 FMX103; the risk that our FMX103 product candidate will not be successfully developed, approved or commercialized; unexpected delays in clinical trials or announcement of results; our ability to effectively and timely conduct clinical trials in light of excess costs or unfavorable results of clinical trials; delays or denial in the U.S. regulatory approval process and the risks that the current or planned clinical trials will be insufficient to support future regulatory submissions or to support marketing approval in the United States of our product candidates; additional competition in the acne and dermatology markets; risks associated with denial of reimbursement by third party payors; our ability to raise additional capital; and our ability to recruit and retain key employees. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. Although we believe these forward-looking statements are reasonable, they speak only as of the date of this release and we undertake 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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