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 17, 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 October 17, 2019, Foamix Pharmaceuticals Ltd. issued a press release entitled "Foamix Announces FDA Acceptance of its New Drug Application for FMX103 Minocycline Foam 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 Announces FDA Acceptance of its New Drug Application for FMX103 Minocycline Foam for the Treatment of Moderate-to-Severe Papulopustular Rosacea," dated October 17, 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 17, 2019

FOAMIX PHARMACEUTICALS LTD.

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

Exhibit 99.1

Foamix Announces FDA Acceptance of its New Drug Application for FMX103 Minocycline Foam for the Treatment of Moderate-to-Severe Papulopustular Rosacea

PDUFA Target Action Date of June 2nd, 2020

Rehovot, Israel, and Bridgewater, NJ – October 17th, 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 the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for FMX103 (minocycline topical foam 1.5%) topical foam. Foamix is seeking approval of FMX103 for the treatment of moderate-to-severe papulopustular rosacea in adults. The FDA has set June 2nd, 2020 as the Prescription Drug User Fee Act (PDUFA) action date.

"The FDA's acceptance of the FMX103 NDA is another important milestone for Foamix as the company evolves into a fully integrated pharmaceutical company with clinical, development, and commercial capabilities. We look forward to working closely with the FDA throughout the review process," said David Domzalski, Chief Executive Officer. "The application includes what we believe is a strong and complete clinical data package. Rosacea is a challenging condition to treat for patients and healthcare providers. If approved, FMX103 has the potential to address significant unmet needs for those who are burdened with rosacea."

The NDA submission is supported by the previously communicated results from two 12-week double-blind Phase 3 efficacy and safety trials (Studies FX2016-11 and FX2016-12) and one 40-week open-label safety extension trial (Study FX2016-13). In Studies FX2016-11 and FX2016-12, FMX103 met both co-primary endpoints, demonstrating statistically significant improvements in inflammatory lesion count and Investigator Global Assessment (IGA) treatment success. No treatment-related serious adverse events have been identified in the FMX103 clinical development program, where the most common adverse event was upper respiratory tract infection. The NDA submission also incorporates information from Phase 1 and Phase 2 clinical trials, chemistry manufacturing and controls, and data from nonclinical toxicology studies.

About Foamix Pharmaceuticals

Foamix is a late clinical-stage 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 foam. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in the Company's dermatology products in late stage development: FMX101 for the potential treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older, and FMX103 for the potential treatment of moderate-to-severe papulopustular rosacea in adults.

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 contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the Company's submission of a NDA for FMX103, its future development plans regarding FMX103, the PDUFA date of FMX103, the potential approval of FMX103 by the FDA and the potential for FMX103 to address a significant unmet need. 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 our product candidates; the risk that our product candidates 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 quarterly report on Form 10-Q, 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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