
**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): May 7, 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))

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.

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

Item 2.02. Results of Operations and Financial Condition

On May 7, 2019, Foamix Pharmaceuticals Ltd. (the “Company”) issued a press release announcing its financial results for its first quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 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 (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure

On May 7, 2019, the Company issued a press release announcing its financial results for its first quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 hereto.

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 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

Exhibit No. Description

99.1 [Press release of the Company titled “Foamix Reports First Quarter 2019 Financial Results and Provides Corporate Update.” dated May 7, 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: May 7, 2019

FOAMIX PHARMACEUTICALS LTD.

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



Foamix Reports First Quarter 2019 Financial Results and Provides Corporate Update

*FDA Accepts NDA for FMX101, Sets October 20, 2019 as PDUFA Action Date
Conference Call Scheduled for Wednesday May 8th at 8:30am Eastern Time*

Rehovot, Israel, and Bridgewater, NJ, May 7, 2019 – Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX) (“Foamix Pharmaceuticals” or the “Company”), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical therapies to address unmet needs in dermatology, today announced financial results for the first quarter ended March 31, 2019 and provided a corporate update.

“Foamix has achieved a number of important milestones so far in 2019,” said David Domzalski, CEO of Foamix. “The New Drug Application (NDA) for our most advanced candidate, FMX101 for acne, has been accepted for review by the FDA, putting us on track for our first potential approval in the U.S. in October this year. We are also on track to file our second NDA, for FMX103 in papulopustular rosacea, by mid-year. Our pipeline is also advancing, and we are building our sales and marketing capabilities as we prepare to launch FMX101 early next year.”

First Quarter and Recent Corporate and Regulatory Update:

- The U.S. Food & Drug Administration (FDA) accepted for review the NDA for FMX101. Foamix is seeking approval of FMX101 for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients nine years of age and older.
 - The FDA has set October 20th, 2019 as the Prescription Drug User Fee Act (PDUFA) action date.
- Two posters featuring FMX101 have been accepted for presentation at the Annual Meeting of the Society for Investigative Dermatology to be held May 8-11, 2019, in Chicago:
 - *The Impact of FMX101 on the Physical Properties of Human Sebum: Comparison of an Oil-Based Formulation vs an Oil-in-Water Emulsion*
 - *Assessing Bacterial Susceptibility of FMX101 4% Topical Minocycline Foam*
- Reported top-line results from study FX2016-13 which evaluated the long-term safety of FMX103 in moderate-to-severe papulopustular rosacea. This 40-week open-label safety study provided positive safety data with continuing development of efficacy beyond the initial 12 weeks of therapy. 81.6% of patients who completed the study achieved clear or almost clear skin at Week 52.
- Announced, along with LEO Pharma A/S, the settlement of the Hatch-Waxman litigation with Perrigo, relating to Finacea[®] foam. Terms of the settlement were not disclosed.

Financial Results for the First Quarter Ended March 31, 2019

Revenues

Total revenues for the first quarter ended March 31, 2019 were \$308 thousand, a \$598 thousand, or 66% decrease, from the \$906 thousand in total revenues recorded in the first quarter ended March 31, 2018, as a result of a decrease in the royalty payment from our partner LEO Pharma A/S for sales of Finacea[®] foam.

Research and Development Expenses

Research and development expenses for the first quarter ended March 31, 2019 were \$10.8 million, a \$12.0 million, or 52.6% decrease, compared to \$22.8 million for the first quarter ended March 31, 2018. The decrease in research and development expenses resulted primarily from a decrease of \$13.8 million in clinical trial costs due to the completion of the FMX101 and FMX103 clinical trials, offset by an increase of \$1.2 million in payroll, payroll-related and consultant expenses.

Selling, General and Administrative Expenses

General and administrative expenses for the first quarter ended March 31, 2019 were \$5.3 million, an increase of \$1.5 million, or 39.4%, compared to \$3.8 million for the first quarter ended March 31, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of \$1.4 million in expenses mostly relating to pre-commercialization activities and market research.

Net Loss

Net loss for the first quarter ended March 31, 2019 was \$15.2 million, or \$0.28 per diluted share, compared to a net loss of \$26.0 million, or \$0.69 per diluted share, in the first quarter ended March 31, 2018, a decrease of \$10.8 million, or 42%.

Cash & Cash Equivalents

At March 31, 2019, the Company had cash and cash equivalents of \$82.9 million, compared to cash and cash equivalents of \$99.4 million at December 31, 2018. The Company currently anticipates that its existing cash and investments we will be able to fund planned operating expenses and capital expenditure requirements through mid-2020. These planned expenses include: (a) any pre-commercialization and launch preparations for FMX101, assuming the Company receives regulatory approval, (b) full development and filing of an NDA for FMX103, which the Company expects to submit in mid-2019 and (c) certain pipeline development activities.

Conference Call & Webcast

Wednesday, May 8th @ 8:30am Eastern Time

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13689852
Webcast:	http://public.viavid.com/index.php?id=134118

A replay of the call will be archived on the Company's website at www.foamix.com promptly after the conference call.

About Foamix

Foamix is a specialty pharmaceutical company focused on the development and commercialization of proprietary, innovative and differentiated topical drugs for dermatological therapy. Our leading clinical stage product candidates are FMX101, our novel minocycline foam being developed for the treatment of moderate-to-severe acne and FMX103, our novel minocycline foam being developed for the treatment of rosacea. We continue to pursue research & development of our proprietary, innovative topical technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies.

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

Company's expectations regarding its cash runway and expectations regarding future uses of cash; the review, potential regulatory approval and commercial launch of FMX101, including the potential timing of FDA review of the Company's NDA seeking approval of FMX101; and statements regarding the regulatory submission and clinical development of the Company's other product candidates including 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 the Company's clinical trials are not sufficient to support registration or marketing approval of its product candidates; the risk that its 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; additional competition in the dermatology markets; risks associated with denial of reimbursement by third party payors; expectations regarding the Company's commercialization efforts and the sufficiency and availability of funding to support its business strategy and operations. 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 the Company's most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in its 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 it 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.

Contact:

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FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,994	\$ 27,868
Restricted cash	250	250
Short term bank deposits	24,155	24,047
Investment in marketable securities	39,122	46,669
Restricted investment in marketable securities	276	268
Accounts receivable:		
Trade	1,168	1,066
Other	1,209	999
TOTAL CURRENT ASSETS	85,174	101,167
NON-CURRENT ASSETS:		
Investment in marketable securities	-	150
Restricted investment in marketable securities	137	133
Property and equipment, net	2,297	2,235
Operating lease right of use assets	1,934	-
Other	17	46
TOTAL NON-CURRENT ASSETS	4,385	2,564
TOTAL ASSETS	\$ 89,559	\$ 103,731
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 5,657	\$ 6,327
Operating lease liabilities	914	-
Other	2,859	4,141
TOTAL CURRENT LIABILITIES	9,430	10,468
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	397	367
Operating lease liabilities	1,023	-
Other liabilities	714	714
TOTAL LONG-TERM LIABILITIES	2,134	1,081
TOTAL LIABILITIES	11,564	11,549
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 90,000,000 Ordinary Shares as of March 31, 2019 and December 31, 2018; issued and outstanding: 54,419,323 and 54,351,140 Ordinary Shares as of March 31, 2019 and December 31, 2018, respectively	2,334	2,331
Additional paid-in capital	306,266	305,303
Accumulated deficit	(230,613)	(215,409)
Accumulated other comprehensive income (loss)	8	(43)
TOTAL SHAREHOLDERS' EQUITY	77,995	92,182
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 89,559	\$ 103,731

FOAMIX PHARMACEUTICALS LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Three months ended March 31,	
	2019	2018
REVENUES	\$ 308	\$ 906
OPERATING EXPENSES:		
Research and development	10,848	22,825
Selling, general and administrative	5,344	3,801
TOTAL OPERATING EXPENSES	16,192	26,626
OPERATING LOSS	15,884	25,720
FINANCE INCOME, net	(504)	(73)
LOSS BEFORE INCOME TAX	15,380	25,647
INCOME TAX	(176)	330
NET LOSS FOR THE YEAR	\$ 15,204	\$ 25,977
LOSS PER SHARE BASIC AND DILUTED	\$ 0.28	\$ 0.69
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	54,370	37,541