
**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): February 28, 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.

Item 2.02. Results of Operations and Financial Condition

On February 28, 2019, Foamix Pharmaceuticals Ltd. (the “Company”) issued a press release announcing its financial results for its fourth quarter ended December 31, 2018. 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 February 28, 2019, the Company issued a press release announcing its financial results for its fourth quarter ended December 31, 2018. 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 Fiscal Year 2018 Financial Results and Provides Corporate Update.” dated February 28, 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: February 28, 2019

FOAMIX PHARMACEUTICALS LTD.

By: /s/ Mutya Harsch

Mutya Harsch
Chief Legal Officer



Foamix Reports Fiscal Year 2018 Financial Results and Provides Corporate Update

Conference Call Scheduled for Friday, March 1 at 8:30am Eastern Time

Rehovot, Israel, and Bridgewater, NJ, February 28, 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 year ended December 31, 2018 and provided key corporate updates.

“Late last year, we reached a major milestone with the filing of our first NDA for our most advanced candidate, FMX101, for acne,” said David Domzalski, CEO of Foamix. “This puts us in sight of our first potential commercial approval in the fourth quarter this year. We plan to file a second NDA, for FMX103 for rosacea, in mid-year. Both of these candidates address dermatological indications with large patient populations in need of differentiated, more effective treatment alternatives. We have both the resources and management team in place to transition to commercialization, and we see a great opportunity to serve the dermatology community as well as create value for our shareholders.”

Fourth Quarter 2018 and Recent Corporate & Regulatory Update:

- Submitted a New Drug Application (NDA), via a 505(b)(2) regulatory pathway, to the U.S. Food and Drug Administration (FDA) seeking approval for FMX101 for the treatment of moderate-to-severe acne.
 - Announced topline results from its Phase 3 program evaluating FMX103 1.5% minocycline foam, in the treatment of moderate-to-severe papulopustular rosacea.
 - o Studies FX2016-11 and FX2016-12 met both co-primary endpoints of (1) absolute change from baseline in inflammatory lesion count at Week 12, and (2) Investigator Global Assessment (“IGA”) treatment success at Week 12, defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from baseline.
 - Reported data from study FX2016-13 evaluating the long-term safety of FMX103 in moderate-to-severe papulopustular rosacea demonstrating positive safety data for its Phase 3 open-label safety with continuing development of efficacy beyond the initial 12 weeks of therapy.
 - Announced, during an R&D Day in New York on January 24th 2019, the company plans to initiate a Phase 2 study during Q2, 2019, for FCD105, a minocycline plus adapalene combination foam product for acne.
 - Strengthened Board of Directors and Management Team
 - o Matt Wiley appointed as Chief Commercial Officer. In this newly created position, Mr. Wiley is responsible for the development and execution of commercial strategies of the Company’s product portfolio, including the planned launches of FMX101 for acne and FMX103 for rosacea.
 - o Sharon Barbari and Anthony Bruno appointed to Board of Directors.
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Financial Results for the Year Ended December 31, 2018

Revenues

Total revenues for the year ended December 31, 2018 were \$3.6 million, compared to \$3.7 million in the year ended December 31, 2017. The revenues for the year ended December 31, 2018 consisted of royalty payments in the amount of \$3.5 million and \$62 thousand from contingent payments.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2018 were \$64.5 million, an increase of \$6.7 million, or 11.6%, compared to \$57.8 million for the year ended December 31, 2017. The increase in research and development expenses resulted primarily from an increase of \$5 million in costs relating predominantly to FMX101 and FMX103 clinical trials; an increase of \$0.6 million in consultant expenses and an increase of \$0.4 million in payroll and payroll related expenses mostly due to increase in headcount, bonuses and share based compensation expenses.

Selling, General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2018 were \$14.0 million, an increase of \$2.5 million, or 21.7%, compared to \$11.5 million for the year ended December 31, 2017. The increase in selling, general and administrative expenses resulted primarily from an increase of \$1.1 million in consultant expenses mostly relating to pre-commercialization activities and an increase of \$0.7 million in payroll and other payroll-related expenses mostly due to increase in headcount, bonuses and share based compensation expenses.

Net Loss

Net loss for the year ended December 31, 2018 was \$74.2 million, or (\$1.70) per diluted share, compared to \$65.7 million, or (\$1.76) per diluted share for the year ended December 31, 2017.

Cash & Cash Equivalents

At December 31, 2018, the Company had \$99.4 million in cash and investments compared to \$76.4 million at the end of December 2017. 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

Friday, March 1st @ 8:30am Eastern Time

Toll Free: 877-407-0784
International: 201-689-8560
Conference ID: 13687390
Webcast: <http://public.viavid.com/index.php?id=133210>

Replays, Available through March 15th:

Toll-Free: 844-512-2921
International: 412-317-6671
Conference ID: 13687390

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

A copy of the Company's 2019 Annual Report will be filed with the Securities and Exchange Commission and posted on the Company's website at <http://investors.foamix.com/sec-filings>. You may request a copy of our Form 10-K, at no cost to you, by writing to the Corporate Secretary of the Company at 2 Holzman Street, Weizmann Science Park Rehovot 7670402, Israel or by calling the Company at +972-8-9316233.

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 for the treatment of moderate-to-severe acne and FMX103, our novel minocycline foam for the treatment of rosacea. We continue to pursue research & development of our proprietary, innovative foam 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 FMX101 and FMX103 and the Company's commercial activities. 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 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.

Contact:

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

	Year ended December 31		
	2018	2017	2016
REVENUES	3,595	3,669	\$ 5,527
COST OF REVENUES	-	13	59
GROSS PROFIT	3,595	3,656	5,468
OPERATING EXPENSES:			
Research and development	64,474	57,779	25,897
Selling, general and administrative	14,013	11,491	9,221
TOTAL OPERATING EXPENSES	78,487	69,270	35,118
OPERATING LOSS	74,892	65,614	29,650
FINANCE INCOME, net	(941)	(1,063)	(701)
LOSS BEFORE INCOME TAX	73,951	64,551	28,949
INCOME TAX	212	1,164	387
NET LOSS FOR THE YEAR	74,163	65,715	\$ 29,336
LOSS PER SHARE BASIC AND DILUTED	1.70	1.76	\$ 0.91
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	43,660	37,376	32,263

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

	Dec-31	
	2018	2017
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	27,868	15,956
Restricted cash	250	250
Short term bank deposits	24,047	19,443
Investment in marketable securities	46,669	31,797
Restricted investment in marketable securities	268	290
Accounts receivable:		
Trade	1,066	996
Other	999	772
TOTAL CURRENT ASSETS	101,167	69,504
NON-CURRENT ASSETS:		
Investment in marketable securities	150	8,533
Restricted investment in marketable securities	133	143
Property and equipment, net	2,235	2,042
Other	46	32
TOTAL NON-CURRENT ASSETS	2,564	10,750
TOTAL ASSETS	103,731	80,254

	Dec-31	
	2018	2017
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	6,327	6,436
Deferred revenues	-	62
Other	4,141	3,730
TOTAL CURRENT LIABILITIES	10,468	10,228
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	367	437
Other liabilities	714	988
TOTAL LONG-TERM LIABILITIES	1,081	1,425
TOTAL LIABILITIES	11,549	11,653
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.16 par value - authorized: 90,000,000 ordinary shares as of December 31, 2018 and December 31, 2017; issued and outstanding: 54,351,140 and 37,498,128 ordinary shares as of December 31, 2018 and December 31, 2017, respectively	2,331	1,576
Additional paid-in capital	305,303	208,364
Accumulated deficit	(215,409)	(141,281)
Accumulated other comprehensive loss	(43)	(58)
TOTAL SHAREHOLDERS' EQUITY	92,182	68,601
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	103,731	80,254