
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 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))

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 2.02. Results of Operations and Financial Condition

On August 7, 2019, Foamix Pharmaceuticals Ltd. (the “Company”) issued a press release announcing its financial results for its second quarter ended June 30, 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 August 7, 2019, the Company issued a press release announcing its financial results for its first quarter ended June 30, 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 Second Quarter 2019 Financial Results and Provides Corporate Update.” dated August 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: August 7, 2019

FOAMIX PHARMACEUTICALS LTD.

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



Foamix Reports Second Quarter 2019 Financial Results and Provides Corporate Update

Conference Call Scheduled for Thursday, August 8th at 8:30am Eastern Time

Rehovot, Israel, and Bridgewater, NJ, August 7, 2019 – Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) (“Foamix” 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 three and six months ended June 30, 2019 and provided a corporate update.

“We continue to make excellent progress advancing our late stage pipeline in dermatology and in making preparations to become a commercial organization,” said David Domzalski, CEO of Foamix. “The FDA has established October 20, 2019 as the Prescription Drug User Fee Act (“PDUFA”) action date for FMX101 in acne, setting us up for potential approval of our first product later this year. Earlier this week, we submitted an NDA for our second product candidate, FMX103 for the treatment of papulopustular rosacea. We were pleased, also, to have secured up to \$64 million in financing from two of our longstanding shareholders, Perceptive Advisors and OrbiMed. Combined with our current cash position, we believe these investments, along with the future access to capital which these transactions provide, will allow us to fund the commercial launches of FMX101 and FMX103, pending FDA approval of these products.”

Second Quarter and Recent Corporate and Regulatory Update:

- Submitted a New Drug Application (“NDA”) to U.S. FDA for FMX103 for the treatment of moderate-to-severe papulopustular rosacea
 - Submission is supported by the 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 treatment scores. It also incorporates information on chemistry manufacturing and controls, and data from non-clinical toxicology studies.
 - Publication of Phase 3 study FX2017-22 (“Study 22”) of FMX101 in acne in the Journal of the American Academy of Dermatology.
 - Study 22 was conducted by Foamix to support the NDA submission of FMX101, which is currently under review by the FDA for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients nine years of age and older.
 - Two posters featuring FMX101 and the FMX101 vehicle were presented at the Annual Meeting of the Society for Investigative Dermatology, held May 8-11, 2019, in Chicago.
 - Completed Clinical Investigator Training Meeting for Phase 2 study of FCD105 (3% minocycline + 0.3% adapalene foam) for the treatment of moderate-to-severe acne vulgaris
 - Secured up to \$64 million in financing in transactions with Perceptive Advisors and OrbiMed.
-

Financial Results for the Second Quarter Ended June 30, 2019

Revenues

The Company reported no revenues for the quarter ended June 30, 2019, compared to \$1.0 million in the quarter ended June 30, 2018. The decrease was a result of reduced royalty payments from LEO Pharma A/S (“LEO”), the licensee to certain of our patents for Finacea foam, due to a failure on the part of LEO’s active pharmaceutical ingredient (“API”) manufacturer to meet the required specifications in the finished product. LEO has informed the Company that they are working diligently to address the issue in order to be able to produce supply of the finished product that meets the required specifications to meet the demand for Finacea in the market. This supply chain issue for Finacea is not related to the manufacturing, production or supply of any of the Company’s products, including FMX101 and FMX103.

Research and Development Expenses

Research and development expenses for the quarter ended June 30, 2019 were \$12.6 million, representing a decrease of \$4.2 million, or 25%, compared to \$16.8 million for the quarter ended June 30, 2018. The decrease in research and development expenses resulted primarily from a decrease of \$6.0 million in clinical trial expenses due to the completion of FMX101 and FMX103 clinical trials, offset by an increase of \$0.5 million in payroll and payroll-related expenses due to an increase in headcount and salaries, and a \$0.9 million increase in consulting expenses. Research and development expenses for the quarter ended June 30, 2019 include materials, in the amount of \$1.2 million, purchased for the manufacturing of commercial and sample products. If the Company obtains regulatory approval for its product candidates, these types of costs will be capitalized as inventory.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the quarter ended June 30, 2019 were \$6.8 million, an increase of \$3.9 million, or 134%, compared to \$2.9 million for the quarter ended June 30, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of \$2.5 million in expenses mostly relating to pre-commercialization activities and market research, in addition to an increase of \$1.4 million in payroll and payroll-related expenses.

Net Loss

Net loss for the second quarter ended June 30, 2019 was \$19.0 million, or \$0.35 per diluted share, compared to a net loss of \$18.6 million, or \$0.46 per diluted share, in the second quarter ended June 30, 2018.

Cash & Cash Equivalents

At June 30, 2019, Foamix had cash and cash equivalents of \$70.0 million, compared to cash and cash equivalents of \$99.4 million at December 31, 2018. In July 2019, the Company secured up to \$64 million in financing from Perceptive Advisors and OrbiMed. The financing consisted of term loans of up to \$50 million under a Credit Agreement, with \$15 million provided immediately upon satisfaction of certain closing conditions, \$20 million available upon the achievement of certain regulatory milestones, and \$15 million available upon the achievement of certain revenue milestones. Additionally, the Company received \$14 million in gross proceeds from Perceptive Advisors through a registered direct offering of ordinary shares. Combined with the cash position at June 30, 2019, the Company believes that these financings, along with future access to capital which these transactions provide, will support the commercial launches for FMX101 and FMX103, pending FDA approval.

Financial Results for the Six Months Ended June 30, 2019

Revenues

Total revenues decreased by \$1.6 million, or 84%, to \$0.3 million in the six months ended June 30, 2019, compared to \$1.9 million in the six months ended June 30, 2018. The decrease is due to the inability of LEO's API contract manufacturer for Finacea to meet the required specifications for the finished product, as described above.

Research and Development Expenses

The Company's research and development expenses for the six months ended June 30, 2019 were \$23.4 million, representing a decrease of \$16.3 million, or 41%, compared to \$39.7 million for the six months ended June 30, 2018. The decrease in research and development expense resulted primarily from a decrease of \$19.3 million in clinical trial expenses due to the completion of FMX101 and FMX103 clinical trials, offset by an increase of \$1.0 million in payroll and payroll-related expenses due to an increase in headcount and salaries, and a \$1.6 million increase in consulting expenses. Research and development expenses for the six months ended June 30, 2019 include materials, in the amount of \$1.2 million, purchased for manufacturing of commercial and sample products. If the Company obtains regulatory approval for its product candidates these types of costs will be capitalized as inventory.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the six months ended June 30, 2019 were \$12.1 million, representing an increase of \$5.4 million, or 81%, compared to \$6.7 million for the six months ended June 30, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of \$3.9 million in expense mostly relating to pre-commercialization activities and market research in addition to an increase of \$1.5 million in payroll and payroll-related expenses.

Net Loss

Net loss for the six months ended June 30, 2019 was \$35.2 million, or \$0.63 per diluted share, compared to a net loss of \$44.5 million, or \$1.15 per diluted share, in the same six months ended June 30, 2018.

Conference Call & Webcast

Thursday, August 8th @ 8:30amET

Toll Free: 855-327-6838
International: 604-235-2082
Conference ID: 10007347
Webcast: <http://public.viavid.com/index.php?id=135538>

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 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.

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 and Exchange Commission ("SEC"), public conference calls, and webcasts.

Forward Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions created by those sections. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions, expectations, forecasts, beliefs or intentions related to the Company's cash runway and expectations regarding future uses of cash, the clinical development, potential regulatory approval and commercial launch of FMX101, including the potential timing of FDA review of the Company's NDA seeking approval of FMX101, the regulatory submission and clinical development of FMX103, and the availability of additional financing under the Credit Agreement. Forward-looking statements are based on our current knowledge and our 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, unexpected delays in clinical trials, announcement of results or submissions of NDAs to the FDA, excess costs or unfavorable results of clinical trials, delays or denial in the FDA approval process, including specifically, FDA approval of FMX101 and FMX103, respectively; additional competition in the acne and dermatology markets, denial of reimbursement by third party payors or inability to raise additional capital, our ability to recruit and retain key employees and our ability to stay in compliance with applicable laws, rules and regulations. We discuss many of these risks in greater detail in our annual and other periodic filings with the SEC, including under the heading "Risk Factors" in our most recent annual report. Although we believe 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.

Contact:

Ilan Hadar
Foamix Pharmaceuticals Ltd.
+972-8-9316233
IR@foamixpharma.com

U.S. Investor Relations

Michael Rice
LifeSci Advisors, LLC
646-597-6979
mrice@lifesciadvisors.com

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

	<u>Jun-30</u> <u>2019</u>	<u>Dec-31</u> <u>2018</u>
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 39,085	\$ 27,868
Restricted cash	250	250
Short term bank deposits	16,187	24,047
Investment in marketable securities	14,091	46,669
Restricted investment in marketable securities	282	268
Accounts receivable:		
Trade	308	1,066
Other	1,511	999
TOTAL CURRENT ASSETS	71,714	101,167
NON-CURRENT ASSETS:		
Investment in marketable securities	-	150
Restricted investment in marketable securities	139	133
Property and equipment, net	2,497	2,235
Operating lease right of use assets	1,858	-
Other	18	46
TOTAL NON-CURRENT ASSETS	4,512	2,564
TOTAL ASSETS	\$ 76,226	\$ 103,731
	<u>Jun-30</u> <u>2019</u>	<u>Dec-31</u> <u>2018</u>
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 9,434	\$ 6,327
Operating lease liabilities	999	-
Other	3,664	4,141
TOTAL CURRENT LIABILITIES	14,097	10,468
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	409	367
Operating lease liabilities	882	-
Other liabilities	456	714
TOTAL LONG-TERM LIABILITIES	1,747	1,081
TOTAL LIABILITIES	15,844	11,549
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 135,000,000 and 90,000,000 Ordinary Shares as of June 30, 2019 and December 31, 2018, respectively; issued and outstanding: 54,455,969 and 54,351,140 Ordinary Shares as of June 30, 2019 and December 31, 2018, respectively	2,336	2,331
Additional paid-in capital	307,653	305,303
Accumulated deficit	(249,606)	(215,409)
Accumulated other comprehensive loss	(1)	(43)
TOTAL SHAREHOLDERS' EQUITY	60,382	92,182
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 76,226	\$ 103,731

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

	Six months ended June 30		Three months ended Jun-30	
	2019	2018	2019	2018
REVENUES	\$ 308	\$ 1,870	-	\$ 964
OPERATING EXPENSES:				
Research and development	23,404	39,667	12,556	16,842
Selling, general and administrative	12,147	6,710	6,803	2,909
TOTAL OPERATING EXPENSES	35,551	46,377	19,359	19,751
OPERATING LOSS	35,243	44,507	19,359	18,787
FINANCE INCOME, net	(870)	(352)	(366)	(279)
LOSS BEFORE INCOME TAX	34,373	44,155	18,993	18,508
INCOME TAX	(176)	450	-	120
NET LOSS FOR THE PERIOD	\$ 34,197	\$ 44,605	\$ 18,993	\$ 18,628
LOSS PER SHARE BASIC AND DILUTED	\$ 0.63	\$ 1.15	\$ 0.35	\$ 0.46
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS				
	54,401	38,821	54,426	40,102