
**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): November 11, 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 November 11, 2019, Foamix Pharmaceuticals Ltd. (the “Company”) issued a press release announcing its financial results for its third quarter ended September 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 November 11, 2019, the Company issued a press release announcing its financial results for its third quarter ended September 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 entitled “Foamix Reports Third Quarter 2019 Financial Results and Provides Corporate Update.” dated November 11, 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: November 12, 2019

FOAMIX PHARMACEUTICALS LTD.

By: /s/ Mutya Harsch

Mutya Harsch
Chief Legal Officer



Foamix Reports Third Quarter 2019 Financial Results and Provides Corporate Update

Conference Call and Webcast Scheduled for Monday, November 11th at 8:30am Eastern Time

REHOVOT, Israel, and BRIDGEWATER, N.J., Nov. 11, 2019 -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a 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 nine months ended September 30, 2019 and provided a corporate update.

"The recent FDA approval of AMZEEQ™ for moderate-to-severe acne was a major milestone for Foamix as we transition to becoming a commercial stage organization. AMZEEQ is the first FDA approved topical form of minocycline and its approval represents a significant step in our goal of enhancing the standard of care for acne sufferers in the U.S.," said David Domzalski, Chief Executive Officer of Foamix. "Our commercial team is now in the final stages of preparing for the U.S. launch of AMZEEQ, which is on track to occur in January 2020. We were very pleased also, by the FDA acceptance of our NDA for FMX103, minocycline topical foam for moderate-to-severe papulopustular rosacea, which puts us in sight of potential approval for this product in 2020. Our pipeline continues to advance and we recently initiated a Phase II clinical trial to evaluate the safety and efficacy of our combination foam FCD105 for acne."

"We are excited to announce today that we have entered into a definitive merger agreement with Menlo Therapeutics," added Mr. Domzalski. "The combination of the two companies accelerates our progression to becoming a leading dermatology-focused company with several late-stage assets that can leverage the commercialization infrastructure we are building. Menlo's lead product candidate, serlopitant for pruritus associated with prurigo nodularis, represents a breakthrough therapy for a dermatologic condition with no currently approved treatment options. Its addition means we have the potential for three commercial launches in a two year timeframe. The combination also strengthens our balance sheet. Upon closing we expect to have sufficient cash to fund operations through the first half of 2021."

Third Quarter and Recent Corporate and Regulatory Update:

- Today, announced the signing of a definitive merger agreement with Menlo Therapeutics ("Menlo") to create a combined specialty pharmaceutical company focused on the dermatology space.
 - o Menlo's lead product candidate, serlopitant, for pruritus associated with prurigo nodularis (PN), complements Foamix's existing portfolio and addresses a significant unmet medical need for a serious disease state.
 - o Two Phase III clinical trials of serlopitant in PN are fully enrolled, with results expected in March or April 2020.
 - o Foamix's sales and marketing infrastructure will provide significant leverage for a potential launch of serlopitant.
 - o The pro-forma cash position of the combined companies was \$169.0 million as of September 30, 2019.
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- Received FDA Approval for AMZEEQ™, the first FDA approved topical form of minocycline. AMZEEQ topical foam, 4% (formerly known as FMX101) indicated for the treatment of inflammatory lesions of nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older.
- Long term open label safety portions of studies FX2014-04 and FX2014-05, investigating AMZEEQ in moderate to severe acne, were published in the Journal of Clinical and Aesthetic Dermatology (JCAD).
- Entered into a long-term contract manufacturing & supply agreement for AMZEEQ and product candidate FMX103 with ASM Aerosol Service.
- The Company's New Drug Application ("NDA") for FMX103 minocycline topical foam (1.5%) for the treatment of moderate-to-severe papulopustular rosacea was accepted by the FDA, which has set a targeted PDUFA action date of June 2, 2020.
- Enrolled the first patient in the Phase II clinical trial to evaluate the safety and efficacy of FCD105, a combination topical foam comprising minocycline and adapalene for the treatment of moderate-to-severe acne vulgaris.
- Presented data on topical product candidates for acne and rosacea at 39th Annual Fall Clinical Dermatology Conference, in Las Vegas.
- Intellectual property
 - o The US Patent and Trademark Office (U.S. P.T.O.) issued U.S. Patent No. 10,398,641 relating to method of use of certain minocycline formulations, which expires September 2037 and provides additional coverage for AMZEEQ.
 - o U.S. P.T.O. issued U.S. Patent No. 10,463,742, which provides additional coverage for FCD105 and which expires in 2030.
- Entered into a settlement and license agreement with an affiliate of Teva Pharmaceuticals to resolve pending patent litigation involving Finacea foam.
- Secured up to \$64 million in financing from Perceptive Advisors and OrbiMed.

Financial Results for the Third Quarter Ended September 30, 2019

Revenues

The Company reported no revenues for the quarter ended September 30, 2019, compared to \$0.9 million in the quarter ended September 30, 2018. The decrease was a result of the continued suspension of the manufacturing of Finacea by our partner LEO Pharma A/S ("LEO") 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 us that they are working diligently to address the issue in order to be able to produce sufficient supply of the finished product 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 AMZEEQ, FMX103, or any of the Company's other product candidates.

Research and Development Expenses

Research and development expenses for the quarter ended September 30, 2019 were \$12.5 million, representing a decrease of \$0.6 million, or 4.6%, compared to \$13.1 million for the quarter ended September 30, 2018. The decrease in research and development expenses resulted primarily from a decrease of \$5.0 million in clinical trial expenses due to the completion of AMZEEQ and FMX103 clinical trials, offset by an increase of \$2.6 million in payment related to the submission of our NDA for FMX103, an increase of \$0.8 million in payroll and payroll-related expenses due to an increase in headcount and salaries and \$0.7 million increase in consulting expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the quarter ended September 30, 2019 were \$10.7 million, an increase of \$7.4 million, or 224%, compared to \$3.3 million for the quarter ended September 30, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of \$6.4 million in advisors and consulting expenses in connection with the pre-commercialization activities and an increase of \$0.8 million in payroll and payroll-related expenses due to an increase in headcount.

Net Loss

Our net loss for the three months ended September 30, 2019 was \$23.2 million, as compared to \$15.5 million for the three months ended September 30, 2018, representing an increase of \$7.7 million, or 49.6%. The increase was primarily due to an increase in expenses for pre-commercialization activities.

Cash & Cash Equivalents

At September 30, 2019, Foamix had cash and cash equivalents of \$75.7 million, compared to cash and cash equivalents of \$99.4 million at December 31, 2018.

Financial Results for the Nine Months Ended September 30, 2019

Revenues

Total revenues decreased by \$2.4 million, or 89%, to \$0.3 million for the nine months ended September 30, 2019, compared to \$2.7 million for the nine months ended September 30, 2018. The decrease for the nine months ended September 30, 2019 is due to the ongoing failure of LEO's contract manufacturer to produce the API for Finacea in compliance with the required specifications and quality. LEO has informed us that they are working diligently to address the issue in order to be able to produce supply of the finished product. This supply chain issue for Finacea is not related to the manufacturing, production or supply of any of our other products or product candidates, including AMZEEQ and FMX103.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2019 were \$35.9 million, representing a decrease of \$16.9 million, or 32%, compared to \$52.8 million for the nine months ended September 30, 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2019 were \$22.9 million, representing an increase of \$12.9 million, or 129%, compared to \$10.0 million for the nine months ended September 30, 2018.

Net Loss

Net loss for the nine months ended September 30, 2019 was \$57.4 million, compared to \$60.1 million for the nine months ended September 30, 2018, representing a decrease of \$2.7 million, or 5%. The decrease was primarily due to the decrease in research and development costs related to clinical trials of AMZEEQ and FMX103.

Conference Call & Webcast

The company will host a conference call and live audio webcast today to discuss the merger with Menlo and the financial results. This call will take the place of the company's previously announced earnings call, which had been scheduled for Tuesday, November 12.

Monday, November 11th @ 8:30amET

Toll free: 877-407-0784

Int'l Investors Dial: 201-689-8560

Investors in Israel Dial: 1 809 406 247

Conference ID: 13696725

Webcast with slides: <http://public.viavid.com/index.php?id=137044>

About Foamix Pharmaceuticals

Foamix is a 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, AMZEEQ. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in the Company's dermatology products and in other products currently in development: FMX103 for the potential treatment of moderate to severe papulopustular rosacea and FCD105 for the potential treatment of moderate to severe acne

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.

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Additional Information and Where to Find It

Menlo plans to file a Registration Statement on Form S-4 containing a joint proxy statement/prospectus of Menlo and Foamix and other documents concerning the proposed merger with the Securities and Exchange Commission (the "SEC"). BEFORE MAKING ANY VOTING DECISION, MENLO AND FOAMIX'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF MENLO AND FOAMIX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Security holders may obtain a free copy of the joint proxy statement/prospectus (when it is available) and other documents filed by Menlo Foamix with the SEC at the SEC's website at www.sec.gov. Investors and stockholders will be able to obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Menlo and Foamix, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Menlo and Foamix make available free of charge at www.menlotherapeutics.com and www.foamix.com, respectively (in the "Investor Relations" section), copies of materials they file with, or furnish to, the SEC.

Participants in the Solicitation

This press release does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Menlo, Foamix and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of Menlo and Foamix in connection with the proposed merger. Security holders may obtain information regarding the names, affiliations and interests of Menlo's directors and officers in Menlo's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on February 28, 2019, and its definitive proxy statement for the 2019 annual meeting of stockholders, which was filed with the SEC on May 10, 2019. Security holders may obtain information regarding the names, affiliations and interests of Foamix's directors and officers in Foamix's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on February 28, 2019, and its definitive proxy statement for the 2019 annual meeting of stockholders, which was filed with the SEC on March 11, 2019. To the extent the holdings of Menlo's securities by Menlo's directors and executive officers or the holdings of Foamix securities by Foamix's directors and executive officers have changed since the amounts set forth in Menlo's or Foamix's respective proxy statement for its 2019 annual meeting of stockholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger will be included in the joint proxy statement/prospectus relating to the proposed merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Menlo's website at <http://ir.menlotherapeutics.com/financials/sec-filings> and Foamix's website at <https://www.foamix.com/investors/sec-filings>.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities law that are subject to various risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in such statements. Words such as “anticipate,” “expect,” “project,” “intend,” “believe,” and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. Such factors include, but are not limited to: (i) Menlo or Foamix may be unable to obtain stockholder approval as required for the merger; (ii) other conditions to the closing of the merger may not be satisfied; (iii) the merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement of the merger on the ability of Menlo or Foamix to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom Menlo or Foamix does business, or on Menlo’s or Foamix’s operating results and business generally; (v) Menlo’s or Foamix’s respective businesses may suffer as a result of uncertainty surrounding the merger and disruption of management’s attention due to the merger; (vi) the outcome of any legal proceedings related to the merger; (vii) Menlo or Foamix may be adversely affected by other economic, business, and/or competitive factors; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; (ix) risks that the merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the merger; (x) the risk that Menlo or Foamix may be unable to obtain governmental and regulatory approvals required for the transaction, or that required governmental and regulatory approvals may delay the transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; and (xi) other risks to consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all. Additional factors that may affect the future results of Menlo and Foamix are set forth in their respective filings with the SEC, including each of Menlo’s or Foamix’s most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at www.sec.gov. See in particular Item 1A of Part II of Menlo’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 under the heading “Risk Factors” and Item 1A of Part II of Foamix’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 under the heading “Risk Factors.” The risks and uncertainties described above and in Menlo’s most recent Quarterly Report on Form 10-Q and Foamix’s most recent Quarterly Report on Form 10-Q are not exclusive and further information concerning Menlo and Foamix and their respective businesses, including factors that potentially could materially affect its business, financial condition or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements. Readers should also carefully review the risk factors described in other documents that Menlo and Foamix file from time to time with the SEC. The forward-looking statements in this press release speak only as of the date of this press release. Except as required by law, Menlo and Foamix assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

FOAMIX PHARMACEUTICALS LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands, except share data)
(Unaudited)

	September 30	December 31
	2019	2018
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 40,534	\$ 27,868
Restricted cash	250	250
Short term bank deposits	19,141	24,047
Investment in marketable securities	15,333	46,669
Restricted investment in marketable securities	288	268
Accounts receivable:		
Trade	-	1,066
Other	979	999
TOTAL CURRENT ASSETS	<u>76,525</u>	<u>101,167</u>
NON-CURRENT ASSETS:		
Investment in marketable securities	-	150
Restricted investment in marketable securities	143	133
Property and equipment, net	2,809	2,235
Operating lease right of use assets	1,947	-
Other	159	46
TOTAL NON-CURRENT ASSETS	<u>5,058</u>	<u>2,564</u>
TOTAL ASSETS	<u>\$ 81,583</u>	<u>\$ 103,731</u>

	September 30 2019	December 31 2018
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 7,357	\$ 6,327
Operating lease liabilities	1,136	-
Other	4,877	4,141
TOTAL CURRENT LIABILITIES	13,370	10,468
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	419	367
Operating lease liabilities	870	-
Long-term debt	12,939	-
Other liabilities	456	714
TOTAL LONG-TERM LIABILITIES	14,684	1,081
TOTAL LIABILITIES	28,054	11,549
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS- 0.16 par value - authorized: 135,000,000 and 90,000,000 Ordinary Shares as of September 30, 2019 and December 31, 2018, respectively; issued and outstanding: 61,121,087 and 54,351,140 Ordinary Shares as of September 30, 2019 and December 31, 2018, respectively	2,638	2,331
Additional paid-in capital	323,657	305,303
Accumulated deficit	(272,767)	(215,409)
Accumulated other comprehensive loss	1	(43)
TOTAL SHAREHOLDERS' EQUITY	53,529	92,182
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 81,583	\$ 103,731

FOAMIX PHARMACEUTICALS LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	Nine months ended September 30		Three months ended September 30	
	2019	2018	2019	2018
REVENUES	\$ 308	\$ 2,735	\$ -	\$ 865
OPERATING EXPENSES:				
Research and development	35,856	52,809	12,452	13,142
Selling, general and administrative	22,894	10,019	10,747	3,309
TOTAL OPERATING EXPENSES	58,750	62,828	23,199	16,451
OPERATING LOSS	58,442	60,093	23,199	15,586
FINANCE INCOME, net	(908)	(471)	(38)	(119)
LOSS BEFORE INCOME TAX	57,534	59,622	23,161	15,467
INCOME TAX	(176)	463	-	13
NET LOSS FOR THE PERIOD	\$ 57,358	\$ 60,085	\$ 23,161	\$ 15,480
LOSS PER SHARE BASIC AND DILUTED	\$ 1.05	\$ 1.50	\$ 0.41	\$ 0.38
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	54,420	39,932	55,984	40,873