

**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): March 12, 2020

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.)
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2 Holzman Street, Weizmann Science Park Rehovot, Israel (Address of principal executive offices)	7670402 (Zip Code)
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+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 Ordinary Shares, par value NIS 0.16 per share	Ticker symbol(s) FOMX	Name of each exchange on which registered Nasdaq Global Stock Market
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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 March 12, 2020, Menlo Therapeutics Inc. (“Menlo”) issued a press release announcing the financial results for the year ended December 31, 2019 for its wholly-owned subsidiary, Foamix Pharmaceuticals Ltd. (the “Company”). 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 March 12, 2020, Menlo issued a press release announcing the financial results for the year ended December 31, 2019 for the Company. 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

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release entitled “Menlo Reports Financial Results for Subsidiary Foamix Pharmaceuticals for Year Ended December 31, 2019,” dated March 12, 2020.</u>

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: March 12, 2020

FOAMIX PHARMACEUTICALS LTD.

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



Menlo Reports Financial Results for Subsidiary Foamix Pharmaceuticals for Year Ended December 31, 2019

Foamix Became a Wholly Owned Subsidiary of Menlo Therapeutics Upon Closing of Merger on March 9, 2020

Menlo Conference Call and Webcast Scheduled for Thursday, March 12th at 8:30am Eastern Time

BRIDGEWATER, N.J., March 12, 2020 -- Menlo Therapeutics Inc. (Nasdaq: MNLO) (“Menlo” or the “Company”), a specialty pharmaceutical company focused on developing and commercializing proprietary therapies to address unmet needs in dermatology, today announced financial results for its wholly-owned subsidiary, Foamix Pharmaceuticals Ltd. (“Foamix”), for the twelve months ended December 31, 2019 and provided a corporate update. Menlo and Foamix announced the consummation of their merger transaction on March 9, 2020.

Recent pipeline highlights:

- The U.S. Food and Drug Administration (FDA) approved AMZEEQ™ (minocycline) topical foam, 4%, for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in adults and pediatric patients nine years of age and older. AMZEEQ™ is the first topical formulation of minocycline to be approved by the FDA for any condition. Foamix commercially launched AMZEEQ™ in the U.S. in January 2020.
- A New Drug Application (NDA) was submitted to the FDA for FMX103 (minocycline) topical foam, 1.5%, for the treatment of papulopustular rosacea in adults. The FDA set a Prescription Drug User Fee Act (PDUFA) action date of June 2, 2020. If approved, FMX103 would be the first minocycline product available for rosacea patients.
- Enrollment has been completed in the ongoing Phase 2 trial for FCD105, a topical combination foam of minocycline and adapalene, currently being evaluated for the treatment of moderate-to-severe acne vulgaris. Topline data from this trial are expected in the second quarter of 2020.
- Serlopitant is being evaluated in two Phase 3 clinical trials for the treatment of pruritus associated with prurigo nodularis (PN). The studies are fully enrolled, with results expected in March or April 2020. Assuming successful completion of the Phase 3 clinical trials, an NDA submission for serlopitant for the treatment of pruritus in PN is planned in the second half of 2020.

Financial Results for Foamix Pharmaceuticals for the Year Ended December 31, 2019

The following financial results pertain only to Menlo's wholly-owned subsidiary, Foamix Pharmaceuticals Ltd. Foamix Pharmaceuticals is filing its last Form 10-K this week, and Menlo does not intend to provide separate financial results for Foamix Pharmaceuticals in the future.

Revenues

Total revenues, consisting primarily of royalties, decreased by \$3.2 million, or 89%, from \$3.6 million in the year ended December 31, 2018 to \$0.4 million in the year ended December 31, 2019, due to the ongoing suspension of the manufacturing and sales of Finacea by LEO, following inadequate supply of quality-compliant batches of the API used in such product.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 were \$51.2 million, representing a decrease of \$13.3 million, or 21%, compared to \$64.5 million for the year ended December 31, 2018. The decrease in research and development expenses resulted primarily from a decrease of \$21.4 million in clinical trial expenses due to the completion of AMZEEQ and FMX103 clinical trials, offset by an increase of \$3.2 million in consulting expenses, an increase of \$2.8 million in payroll and payroll-related expenses due to an increase in headcount and salaries and an increase of \$2.6 million in payments related to the submission of our NDA for FMX103.

Selling, General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2019 were \$45.1 million, representing an increase of \$31.1 million, or 221%, compared to \$14.0 million for the year ended December 31, 2018. The increase in selling, general and administrative expenses resulted primarily from an increase of \$18.0 million in connection with the pre-commercialization activities, an increase of \$5.4 million in payroll and payroll-related expenses due to an increase in headcount as we built out our sales and marketing organization in preparation for the AMZEEQ launch, a \$3.1 million increase in costs relating to the merger transaction with Menlo and a \$2.0 million increase in other advisor and consulting expenses.

Net Loss

Net loss for the year ended December 31, 2019 was \$95.2 million, compared to \$74.2 million for the year ended December 31, 2018, an increase of \$21.0 million, or 28%.

Cash & Cash Equivalents

At December 31, 2019, Foamix had cash and cash equivalents of \$73.4 million, compared to cash and cash equivalents of \$99.4 million at December 31, 2018.

Pro Forma Cash Position for Combined Company

At December 31, 2019, the combined pro forma cash position for Menlo, assuming the merger transaction with Foamix Pharmaceuticals was completed on December 31, 2019, was approximately \$150.5 million.

Conference Call & Webcast

There will be a conference call at 8:30 a.m. Eastern Time on Thursday, March 12th during which management of Menlo will provide a corporate update.

Thursday, March 12th @ 8:30amET

Toll Free: 877-407-0784

International: 201-689-8560

Conference ID: 13700089

Webcast: <http://public.viavid.com/index.php?id=138439>

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

About Menlo

Menlo Therapeutics Inc. recently combined with Foamix Pharmaceuticals Ltd. to form a different type of biopharmaceutical 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 a variety of solutions using its proprietary Molecule Stabilizing Technology (MST™), and has received FDA approval for the world's first topical minocycline, AMZEEQ™ (minocycline) topical foam, 4%. In addition, the Company is focused on the development of serlopitant, a once-daily oral NK1 receptor antagonist, as a novel potential treatment option for pruritus associated with prurigo nodularis.

For more information about Menlo or its investigational products, visit www.menlotherapeutics.com. Menlo may use its website to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Menlo's website in addition to following its press releases, filings with the U.S. Securities and Exchange Commission, public conference calls, and webcasts.

Cautionary Statement Regarding Forward-Looking Statements

This release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding expectations with respect to the anticipated announcement of results of Menlo's clinical trials for pruritus associated with prurigo nodularis, statements regarding the development and commercialization of Menlo's products and product candidates and other statements regarding the future expectations, plans and prospects of Menlo. All statements in this press release which are not historical facts are forward-looking statements. Any forward-looking statements are based on Menlo's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions that could cause actual results to differ materially and adversely from those set forth or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, Menlo's ability to successfully integrate the two companies; the achievement of certain expected cost synergies; the outcome of any legal proceedings related to the merger; the outcome and cost of clinical trials for current and future product candidates, including those for serlopitant; determination by the FDA that results from Menlo's clinical trials are not sufficient to support registration or marketing approval of product candidates; adverse events associated with the commercialization of AMZEEQ™; the outcome of pricing, coverage and reimbursement negotiations with third party payors for AMZEEQ™ or any other products or product candidates that Menlo may commercialize in the future; whether, and to what extent, third party payors impose additional requirements before approving AMZEEQ™ prescription reimbursement; the eligible patient base and commercial potential of AMZEEQ™ or any of Menlo's other product or product candidates; risks that Menlo's intellectual property rights, such as patents, may fail to provide adequate protection, may be challenged and one or more claims may be revoked or interpreted narrowly or will not be infringed; risks that any of Menlo's patents may be held to be narrowed, invalid or unenforceable or one or more of Menlo's patent applications may not be granted and potential competitors may also seek to design around Menlo's granted patents or patent applications; additional competition in the acne and dermatology markets; inability to raise additional capital on favorable terms or at all; Menlo's ability to recruit and retain key employees; and Menlo's ability to stay in compliance with applicable laws, rules and regulations. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Menlo's actual results to differ from those contained in the forward-looking statements, see the sections titled "Risk Factors" in (i) Menlo's most recent annual report on Form 10-K, (ii) Foamix's most recent annual report on Form 10-K and (iii) Menlo's definitive joint proxy statement/prospectus filed with the U.S. Securities and Exchange Commission under Rule 424(b)(3) on January 7, 2020, as well as discussions of potential risks, uncertainties, and other important factors in Menlo's subsequent filings with the U.S. Securities and Exchange Commission. Although Menlo believes these forward-looking statements are reasonable, they speak only as of the date of this announcement and Menlo 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.

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

	December 31	
	2019	2018
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 43,759	\$ 27,868
Restricted cash	825	250
Short term bank deposits	12,102	24,047
Investment in marketable securities	16,246	46,669
Restricted investment in marketable securities	434	268
Trade receivable	135	1,066
Other	1,557	999
Inventory	1,356	-
TOTAL CURRENT ASSETS	76,414	101,167
NON-CURRENT ASSETS:		
Investment in marketable securities	-	150
Restricted investment in marketable securities	-	133
Property and equipment, net	2,885	2,235
Operating lease right of use assets	1,694	-
Other	166	46
TOTAL NON-CURRENT ASSETS	4,745	2,564
TOTAL ASSETS	\$ 81,159	\$ 103,731

	December 31	
	2019	2018
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Trade payables	\$ 19,352	\$ 6,327
Accrued expenses	3,381	351
Employee related obligations	5,231	3,498
Operating lease liabilities	1,092	-
Other	270	292
TOTAL CURRENT LIABILITIES	29,326	10,468
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	424	367
Operating lease liabilities	653	-
Long-term debt	32,725	-
Other liabilities	456	714
TOTAL LONG-TERM LIABILITIES	34,258	1,081
TOTAL LIABILITIES	63,584	11,549
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 135,000,000 and 90,000,000 Ordinary Shares as of December 31, 2019 and December 31, 2018; issued and outstanding: 61,580,544 and 54,351,140 Ordinary Shares as of December 31, 2019 and December 31, 2018, respectively	2,659	2,331
Additional paid-in capital	325,498	305,303
Accumulated deficit	(310,587)	(215,409)
Accumulated other comprehensive income (loss)	5	(43)
TOTAL SHAREHOLDERS' EQUITY	17,575	92,182
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 81,159	\$ 103,731

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

	Year ended December 31		
	2019	2018	2017
REVENUES	\$ 443	\$ 3,595	\$ 3,669
COST OF REVENUES	-	-	13
GROSS PROFIT	443	3,595	3,656
OPERATING EXPENSES:			
Research and development	51,202	64,474	57,779
Selling, general and administrative	45,114	14,013	11,491
TOTAL OPERATING EXPENSES	96,316	78,487	69,270
OPERATING LOSS	95,873	74,892	65,614
FINANCE INCOME	(1,672)	(985)	(1,134)
FINANCE EXPENSES	1,153	44	71
LOSS BEFORE INCOME TAX	95,354	73,951	64,551
INCOME TAX	(176)	212	1,164
NET LOSS FOR THE YEAR	\$ 95,178	\$ 74,163	\$ 65,715
LOSS PER SHARE BASIC AND DILUTED	\$ 1.66	\$ 1.70	\$ 1.76
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	57,292	43,660	37,376