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 11, 2020

Menlo Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38356**	**45-3757789**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

520 U.S. Highway 22, Suite 204
Bridgewater, New Jersey 08807
(Address of principal executive offices, including Zip Code)

(800) 755-7936
(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:

☐ 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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	**MNLO**	**The Nasdaq Stock Market LLC**

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 May 11, 2020, Menlo Therapeutics Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020. The press release is being furnished as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto 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 liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is being furnished herewith.

Exhibit No.	Description
99.1	Press release, dated May 11, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MENLO THERAPEUTICS INC.

Date: May 11, 2020

By: /s/ Mutya Harsch
Mutya Harsch
Chief Legal Officer and General Counsel

Exhibit 99.1

Menlo Reports First Quarter 2020 Financial Results and Provides Business Update

Conference Call Today at 8:30am Eastern Time

BRIDGEWATER, N.J., May 11, 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 the first quarter ended March 31, 2020 and provided a corporate update.

"The launch of AMZEEQ® at the beginning of 2020 marked the transition of Menlo to a commercial company," said Dave Domzalski, Chief Executive Officer of Menlo. "We have been encouraged by the positive reception to AMZEEQ from both physicians and patients, and noted strong increases in weekly prescriptions from launch through early March. During the current economic slowdown, our sales representatives are engaging with healthcare providers virtually and we continue to see positive momentum in our discussions with payors. The recent license agreement we signed with Cutia Therapeutics for the Chinese market underscores the demand that exists for innovative dermatology products in markets outside the U.S. and also provides the company with non-dilutive capital."

"Our NDA for FMX103 for the potential treatment of papulopustular rosacea is currently being reviewed by the FDA, with a PDUFA action date of June 2nd," continued Mr. Domzalski. "If approved, we expect to have two products on the market by the end of this year, providing us with the opportunity to expand our franchise in dermatology and create increased operational leverage for the company."

First Quarter and Recent highlights:

- In January 2020, we commercially launched AMZEEQ (minocycline) topical foam, 4%, for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older. AMZEEQ is the first topical formulation of minocycline to be approved by the FDA for any condition.
- In April 2020, Menlo's wholly owned subsidiary, Foamix Pharmaceuticals Ltd. ("Foamix"), entered into an exclusive licensing agreement with an affiliate of Cutia Therapeutics ("Cutia"), a specialty pharmaceutical company based in mainland China, for the sale of AMZEEQ and its other topical minocycline product candidates, once approved, in Greater China.
  - Foamix will receive an upfront cash payment of $10 million and will be eligible for an additional $1 million payment upon the receipt of marketing approval in China of the first licensed product.
  - Foamix is also entitled to receive mid-single digit royalties on net sales of any licensed products.
- Announced top line results from two Phase 3 clinical trials evaluating the safety and efficacy of oral serlopitant for the treatment of pruritus (itch) associated with prurigo nodularis (PN). The studies did not meet their respective primary endpoints of demonstrating statistically significant reduction in pruritus compared with placebo. Menlo does not intend to pursue further development of serlopitant.
- Entered into a settlement and license agreement to resolve the remaining pending patent litigation involving Finacea® foam.
- Appointed Andrew Saik as Chief Financial Officer and Treasurer.

Financial Results for the First Quarter Ended March 31, 2020

Revenues
Revenues totaled $1.8 million and $0.3 million for the three months ended March 31, 2020 and 2019, respectively. For the three months ended March 31, 2020, revenues were generated from product sales of AMZEEQ, which was launched in January 2020. For the three months ended March 31, 2019, revenues consisted solely of royalty revenues.

Cost of Goods Sold
Cost of goods sold was $0.3 million for the three months ended March 31, 2020. There was no cost of goods sold in the three months ended March 31, 2019 because the revenues in that period consisted solely of royalties, which do not bear related cost of goods sold.

Our gross margin percentage of 85% was favorably impacted during the three months ended March 31, 2020 due to the fact that some inventory was produced prior to FDA approval and therefore expensed in prior periods. If inventory sold during the three months ended March 31, 2020 was valued at cost, our gross margin for the period then ended would have been 79%.

Research and Development Expenses
Our research and development expenses for the three months ended March 31, 2020 were $16.0 million, representing an increase of $5.2 million, or 48%, compared to $10.8 million for the three months ended March 31, 2019. Employee-related expenses increased by $4.7 million, including $3.8 million related to severance expenses associated with legacy Menlo employees, and $0.9 million in increased payroll and related expenses. In addition, clinical and manufacturing costs related to serlopitant, which was acquired in the transaction combining Menlo with Foamix (the “Merger”), increased by $2.2 million, offset by a decrease of $2.2 million related to clinical and manufacturing expenses for AMZEEQ and FMX103.

Selling, General and Administrative Expenses
Our selling, general and administrative expenses for the three months ended March 31, 2020 were $25.4 million, representing an increase of $20.1 million, or 379%, compared to $5.3 million for the three months ended March 31, 2019. Employee-related expenses increased by $10.5 million, consisting of $6.0 million primarily due to the expansion of our employee base, including sales force, to support the growth of our operations and $4.3 million related to severance expenses paid to legacy Menlo employees. We incurred $3.6 million expenses relating to the Merger included in selling, general and administrative expenses. Sales and marketing expenses increased by $1.8 million related to the commercialization of AMZEEQ.

Operating Loss
Our operating loss for the three months ended March 31, 2020 was $39.9 million, compared to an operating loss of $15.9 million for the three months ended March 31, 2019, representing an increase of $24.0 million, or 151%.

Income Taxes
During the three months ended March 31, 2020 we had no tax expenses, as compared to tax benefits of $0.2 million during the three months ended March 31, 2019.

Net Loss
Our net loss for the three months ended March 31, 2020 was $40.2 million or ($0.95) per share, as compared to $15.2 million or ($0.47) per share for the three months ended March 31, 2019, representing an increase of $25.0 million, or 164%. The increase was primarily due to an increase in expenses incurred in connection with our commercial launch of AMZEEQ, Merger expenses and severance expenses for legacy Menlo employees.

Cash & Cash Equivalents
As of March 31, 2020, the combined Company had cash, cash equivalents and investments of $82.7 million. This amount does not include the $10 million upfront payment expected pursuant to the license agreement entered into with Cutia in April 2020.

Conference Call
There will be a conference call at 8:30 a.m. Eastern Time today, Monday, May 11, during which management of Menlo will provide a corporate update.

Monday May 11th @ 8:30amET

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13702832
Webcast:	http://public.viavid.com/index.php?id=139512

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%.

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 financial results of Menlo and 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 the COVID-19 pandemic and its impact on our business operations; adverse events associated with the commercialization of AMZEEQ; the achievement of certain expected cost synergies related to the Merger; the outcome and cost of clinical trials for current and future product candidates; determination by the FDA that results from Menlo's clinical trials are not sufficient to support registration or marketing approval of product candidates; 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; risks related to our indebtedness; 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 section titled "Risk Factors" in Menlo's Quarterly Report on Form 10-Q for the quarter ended March 31, 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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MENLO THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except per share data)
(Unaudited)

	March 31 2020	December 31 2019
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 57,601	$ 43,759
Restricted cash	855	825
Short-term bank deposits	-	12,102
Investment in marketable securities	23,790	16,246
Restricted investment in marketable securities	421	434
Trade receivable	8,333	135
Prepaid and other assets	4,236	1,557
Inventory	3,205	1,356
TOTAL CURRENT ASSETS	98,441	76,414
NON-CURRENT ASSETS:		
Property and equipment, net	2,834	2,885
Operating lease right-of-use assets	1,721	1,694
In-process research & development	50,300	-
Goodwill	4,045	-
Prepaid and other assets	3,192	166
TOTAL NON-CURRENT ASSETS	62,092	4,745
TOTAL ASSETS	$ 160,533	$ 81,159

MENLO THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except per share data)
(Unaudited)

	March 31 2020	December 31 2019
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Trade payables	$ 14,114	$ 19,352
Accrued expenses	12,452	3,381
Employee related obligations	7,803	5,231
Operating lease liabilities	1,009	1,092
Derivative liabilities	1,190	-
Contingent Stock Right	19,636	-
Other	382	270
TOTAL CURRENT LIABILITIES	56,586	29,326
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	411	424
Operating lease liabilities	727	653
Long-term debt	32,818	32,725
Other liabilities	456	456
TOTAL LONG-TERM LIABILITIES	34,412	34,258
TOTAL LIABILITIES	90,998	63,584
COMMITMENTS		
STOCKHOLDERS' EQUITY:		
Common stock: $0.0001 par value; 300,000,000 shares authorized at March 31, 2020 and December 31, 2019, respectively; 61,501,130 and 36,480,314 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	6	3
Additional paid-in capital	420,430	328,154
Accumulated deficit	(350,861)	(310,587)
Accumulated other comprehensive income (loss)	(40)	5
TOTAL SHAREHOLDERS' EQUITY	69,535	17,575
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 160,533	$ 81,159

MENLO THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)
(Unaudited)

	Three months ended March 31	
	2020	**2019**
REVENUES		
Product sales	$ 1,750	$ -
Royalty revenues	-	308
TOTAL REVENUES	1,750	308
EXPENSES		
Cost of goods sold	271	-
Research and development	15,953	10,848
Selling, general and administrative	25,415	5,344
TOTAL EXPENSES	41,639	16,192
OPERATING LOSS	39,889	15,884
FINANCE INCOME	(728)	(536)
FINANCE EXPENSES	1,072	32
LOSS BEFORE INCOME TAX	40,233	15,380
INCOME TAX	-	(176)
NET LOSS FOR THE PERIOD	$ 40,233	$ 15,204
LOSS PER SHARE BASIC AND DILUTED	$ 0.95	$ 0.47
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	42,510	32,209

MENLO THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. dollars in thousands)
(Unaudited)

	Three months ended March 31	
	2020	**2019**
NET LOSS	$ 40,233	$ 15,204
OTHER COMPREHENSIVE LOSS (INCOME):		
Net unrealized losses (gains) from marketable securities	44	(36)
Gains on marketable securities reclassified into net loss	1	-
Net unrealized gains on derivative financial instruments	-	(15)
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	45	(51)
TOTAL COMPREHENSIVE LOSS	$ 40,278	$ 15,153