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): April 21, 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 1.01 Entry into a Material Definitive Agreement.

License Agreement

On April 21, 2020, Foamix Pharmaceuticals Ltd. ("**Foamix**"), a wholly owned subsidiary of Menlo Therapeutics Inc. ("**Menlo**" or the "**Company**"), entered into a License Agreement (the "**License Agreement**") with Cutia Therapeutics (HK) Limited, a company organized and existing under the laws of Hong Kong ("**Cutia**"). Pursuant to the License Agreement, Foamix granted Cutia an exclusive license to obtain regulatory approval of and commercialize the Company's novel AMZEEQ™ (minocycline) topical foam, 4%, in mainland China, Taiwan, Hong Kong and Macau (each a "**Region**" and collectively, the "**Territory**"). In addition, Cutia has been granted an exclusive license to obtain regulatory approval of and commercialize FMX103 and FCD105 (together with AMZEEQ™, the "**Licensed Products**") in the Territory if and as approved by the Food and Drug Administration in the United States. Foamix has agreed to supply the finished Licensed Products to Cutia for clinical and commercial use at an agreed price.

Foamix will receive an upfront cash payment of $10.0 million. Foamix will be entitled to receive an additional $1.0 million following the first regulatory approval of any of the Licensed Products by the National Medical Product Administration of the People's Republic of China. In addition, Foamix will be entitled to receive a royalty on net sales of the Licensed Products in the Territory each quarter. The royalties will be payable on a Licensed Product-by-Licensed Product and Region-by-Region basis and will be paid until the later of (i) ten years from the date of first commercial sale of such Licensed Product in such Region and (ii) the expiration of the last claim of a Foamix patent covering such Licensed Product in such Region.

Foamix may terminate the License Agreement if, among other things, Cutia challenges the validity, enforceability or scope of any Foamix licensed patent in respect of the Licensed Products in a litigation or other court proceeding, subject to certain exceptions. Cutia may terminate the License Agreement at any time upon 90 days' prior written notice. In addition, Cutia may terminate the License Agreement if a regulatory authority in the Territory has ordered Cutia to stop all sales of Licensed Products in the Territory due to a safety concern, subject to certain exceptions. The License Agreement also contains representations and warranties customary for this type of agreement, including with respect to intellectual property rights.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2020.

Item 7.01. Regulation FD Disclosure.

On April 23, 2020, the Company issued a press release entitled "Menlo Therapeutics and Cutia Therapeutics Enter into Exclusive License Agreement for AMZEEQ™ and Approved Topical Minocycline Products in Greater China." A copy of the press release is attached hereto as Exhibit 99.1.

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 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, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. **Other Events.**

As previously disclosed in the Company's Current Report on Form 8-K filed on March 10, 2020, in connection with the completion of the merger (the "**Merger**") between Giants Merger Subsidiary, Ltd., a direct, wholly owned subsidiary of the Company, and Foamix, each warrant to purchase ordinary shares of Foamix was assumed by the Company and converted into a warrant that upon its exercise entitled the holder to receive such number of shares of the Company's common stock ("**Common Stock**") and contingent stock rights ("**CSRs**") that the holder of such warrant would have been entitled to receive had such warrant been exercised prior to the effectiveness of the Merger (each such warrant, a "**Menlo Warrant**").

On April 8, 2020, pursuant to the terms of the Contingent Stock Rights Agreement (the "**CSR Agreement**"), dated as of March 9, 2020, by and between the Company and American Stock Transfer & Trust Company, LLC, each CSR converted into 1.2082 shares of Common Stock (the "**CSR Conversion**"). As contemplated by, and in accordance with the terms of the Menlo Warrant, following the CSR Conversion, each Menlo Warrant was amended and restated (as so amended and restated, the "**Amended and Restated Menlo Warrant**") to reflect that such warrant is no longer exercisable for CSRs but instead entitles the holder to receive upon the exercise of such warrant, such number of additional shares of Common Stock that the CSRs which the holder was entitled to receive upon exercise of the Menlo Warrant would have converted had they been issued to such holder prior to the date of the CSR Conversion.

The foregoing description of each Amended and Restated Menlo Warrant does not purport to be a complete description and is qualified in its entirety by reference to the full text of each Amended and Restated Menlo Warrant, copies of which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is being furnished herewith.

99.1	Press release, dated April 23, 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: April 23, 2020

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

Exhibit 99.1

Menlo Therapeutics and Cutia Therapeutics Enter into Exclusive License Agreement for AMZEEQ™ and Approved Topical Minocycline Products in Greater China

Transaction provides non-dilutive capital including $10M up-front

BRIDGEWATER, New Jersey, April 23, 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 that its wholly-owned subsidiary, Foamix Pharmaceuticals Ltd. (“Foamix”), has entered into a licensing agreement with specialty pharmaceutical company Cutia Therapeutics (HK) Limited, an affiliate of Cutia Therapeutics (“Cutia”) for AMZEEQ™ (minocycline) topical foam, 4% as well as its other topical minocycline product candidates, once approved, on an exclusive basis in Greater China.

Under the terms of the agreement, Cutia will have an exclusive license to obtain regulatory approval of and commercialize AMZEEQ™ and, if approved in the U.S., FMX103 and FCD105 in the Greater China territory. Foamix will supply the finished licensed products to Cutia for clinical and commercial use. Foamix will receive an upfront cash payment of $10 million and will be eligible to receive an additional $1 million payment upon the receipt of marketing approval in China of the first licensed product. Foamix will also receive royalties on net sales of any licensed products.

“We believe that this agreement with Cutia speaks to the importance of our topical minocycline technology and the strong demand for AMZEEQ worldwide,” said David Domzalski, CEO of Menlo. “We intend to partner with other companies outside the U.S. to extend our commercial reach in order to bring AMZEEQ and our topical minocycline product candidates to the hundreds of millions of patients suffering from acne and rosacea.”

“We recognized the value of Foamix’s unique foam technology for dermatology and looked to license its minocycline products as anchor assets as we aim to build China’s leading dermatology platform,” said Lele Zhang, CEO of Cutia. Cutia is a portfolio company of 6 Dimensions Capital, a leading global investment firm with a focus on life sciences and healthcare with over 10B RMB ($1.5B USD) currently under management.

In October 2019, Foamix received U.S. Food and Drug Administration (FDA) approval for AMZEEQ, a minocycline topical foam, 4%, for the treatment of non-nodular inflammatory moderate-to-severe acne vulgaris in adults and pediatric patients 9 years of age and older. In addition to AMZEEQ, the Company is working to develop and commercialize in the U.S. a topical minocycline foam, 1.5% (FMX103) for the potential treatment of inflammatory lesions (papules and pustules) of rosacea in adults, which is currently being reviewed by the FDA with a PDUFA action date of June 2, 2020, and FCD105, a topical foam combination of minocycline and adapalene therapy for the potential treatment of acne vulgaris, which is currently in Phase 2 clinical development with top line results expected in the second quarter of 2020.

With over 200 granted patents worldwide Menlo is a leader in innovative topical technologies and has out-licensed novel delivery platforms to pharmaceutical companies for the development of proprietary topical products containing various active pharmaceutical ingredients.

About AMZEEQ™ (minocycline) topical foam, 4%

Indication

AMZEEQ (minocycline) topical foam, 4% is a topical form of the antibiotic minocycline for the treatment of pimples and red bumps (non-nodular inflammatory lesions) that happen with moderate to severe acne in adults and children 9 years of age and older. AMZEEQ is available by prescription only.

AMZEEQ should not be used for the treatment of infections. It is not known if AMZEEQ is safe and effective in children under 9 years of age. **AMZEEQ is for use on skin only (topical use). AMZEEQ is not for use in the mouth, eyes or vagina.**

Important Safety Information

- AMZEEQ should not be used in people who are allergic to AMZEEQ or any tetracycline medicine. Use of AMZEEQ should be stopped right away if a rash or other allergic symptom occurs.
- AMZEEQ should not be used in women who are pregnant, may become pregnant or are nursing. If a woman becomes pregnant while using AMZEEQ, she should talk to her doctor. Tetracycline medicine when taken by mouth during pregnancy, infancy and/or childhood up to the age of 8 years may permanently discolor teeth (yellow-gray-brown) and may slow the growth of bones.
- AMZEEQ is flammable and fire, flame, and smoking must be avoided when applying and right after applying AMZEEQ.
- People should protect their skin from the sun while using AMZEEQ and avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Use of AMZEEQ should be stopped if skin is sunburned.
- When taken by mouth, minocycline may cause feelings of lightheadedness, dizziness or spinning. People should not drive or operate dangerous machinery if they have these symptoms.

AMZEEQ is a topical foam that contains minocycline, a tetracycline medicine. It is not taken by mouth. However, tetracyclines, when taken by mouth (capsules or tablets), may cause serious side effects, including: diarrhea, including watery or bloody stools; loss of appetite; tiredness; yellowing of the skin or eyes; bleeding more easily than normal; confusion; sleepiness; vision changes, including blurred vision, double vision, or permanent vision loss; unusual headaches; fever; rash; joint pain; body weakness; discoloration or darkening of the skin, scars, teeth, or gums. People should call their doctor right away if these side effects occur.

The most common side effect of AMZEEQ is headache.

These are not all of the possible side effects with AMZEEQ. People should contact their doctor for medical advice about side effects and be sure to tell their doctor about all of their medical conditions and medicines they take before using AMZEEQ.

People are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information.

About Menlo Therapeutics

Menlo Therapeutics Inc. recently combined with Foamix Pharmaceuticals Ltd. (“Foamix”) to form a different type of biopharmaceutical company working to solve some of today’s most difficult therapeutic challenges in dermatology and beyond. Foamix is now a wholly-owned subsidiary of Menlo.

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.

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About Cutia Therapeutics

Cutia Therapeutics (HK) Limited is an affiliate of Cutia Therapeutics group, a specialty pharmaceutical company based in mainland China and focused on becoming China's leading dermatology platform. Cutia is a portfolio company of 6 Dimensions Capital, a leading global investment firm with capabilities in both China and the U.S. to access innovation and build category leaders in healthcare sectors. Among their other "build from scratch" platform companies in China are: Innovent (China's biologics powerhouse), CStone Pharmaceuticals (oncology therapeutics), Ocumension ("The" China ophthalmology platform) and Cutia Therapeutics (China's leading dermatology platform).

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 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, any adverse effects related to the global COVID-19 pandemic; the ability of Menlo or any of its partners to achieve a desirable outcome in clinical trials for current and future product candidates; determination by the FDA or any other regulatory authority that results from our 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 or any of its partners 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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