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 2, 2019

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)	(I. R. S. Employer Identification No.)

200 Cardinal Way, 2nd Floor
Redwood City, California 94063
(Address of principal executive offices, including ZIP code)

(650) 486-1416
(Registrant's telephone number, including area code)

Not Applicable
(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))

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. ☒

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

Item 2.02. Results of Operations and Financial Condition.

On May 2, 2019, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. 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.

Exhibit Number	Exhibit Description
99.1	Press release dated May 2, 2019

SIGNATURE

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.

Menlo Therapeutics, Inc.

/s/ Kristine Ball

Date: May 2, 2019

By: Kristine Ball
Senior Vice President, Corporate Strategy and
Chief Financial Officer

Exhibit 99.1

Menlo Therapeutics Reports First Quarter 2019 Financial Results

REDWOOD CITY, Calif., May 2, 2019 -- Menlo Therapeutics Inc. (NASDAQ: MNLO), a late-stage biopharmaceutical company focused on the development of serlopitant for the treatment of pruritus (itch), today announced financial results for the first quarter ended March 31, 2019 and provided an update on its clinical development programs.

"2019 is a year of execution for us as we prepare for multiple data events and a potential NDA filing for serlopitant next year," said Steve Basta, Menlo's Chief Executive Officer. "Our Phase 3 clinical trials in pruritus associated with prurigo nodularis and our Phase 2 clinical trial in chronic pruritus of unknown origin are enrolling well. We are working with the FDA to design our Phase 3 program in pruritus associated with psoriasis and plan to initiate this program in 2019. We are also completing extensive work to prepare for our planned 2020 NDA for pruritus associated with prurigo nodularis if the ongoing Phase 3 trials are successfully completed."

Clinical Program Updates

Prurigo Nodularis

- In January 2019, Menlo announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for serlopitant for the treatment of pruritus associated with prurigo nodularis (PN).
- Menlo is currently enrolling patients in two Phase 3 clinical trials (one in the U.S. and one in Europe) to evaluate serlopitant as a treatment for pruritus associated with PN. Each trial will enroll approximately 280 patients. More than 160 patients have been enrolled in each trial to date. Results from these trials are expected in the first half of 2020.
- Menlo is also currently enrolling patients in a 52-week, multicenter, open-label safety study of serlopitant for the treatment of pruritus associated with PN, atopic dermatitis, or psoriasis. The objective of this study is to provide long-term safety data for serlopitant in adults with pruritus, consistent with ICH and FDA guidelines, which recommend that drugs being developed for long-term treatment be evaluated for safety in at least 100 patients treated for 12 months and 300 patients treated for 6 months. Approximately 300 patients have been enrolled in this open-label study to date.

Psoriasis

- Menlo has completed an initial end of Phase 2 meeting with the FDA and is in ongoing communications with the FDA regarding the planned Phase 3 program for pruritus associated with psoriasis, which is anticipated to begin in 2019.

Chronic Pruritus of Unknown Origin

- Menlo is conducting a Phase 2 clinical trial in patients with chronic pruritus of unknown origin and expects to enroll approximately 200 patients in this trial.
- Menlo began enrollment of patients in this Phase 2 trial in the first quarter of 2019.
- Menlo anticipates that results from this trial will be available by mid-2020.

Financial Results

First Quarter 2019 Financial Results

Menlo reported a net loss attributable to common stockholders of $18.9 million for the first quarter of 2019, compared to a net loss of $12.7 million for the same period in 2018.

Collaboration and license revenue was zero in the first quarter of 2019 compared to $0.5 million for the same period in 2018. The decrease in collaboration and license revenue was due to the termination of the Collaboration Agreement with JT Torii in June 2018.

Research and development expenses were $15.9 million in the first quarter of 2019, compared to $11.0 million for the same period in 2018. The increase was primarily due to an increase in manufacturing expenses, clinical trial expenses, an increase in personnel expenses as a result of an increase in our employee headcount and stock-based compensation expense, and an increase in medical affairs related costs.

General and administrative expenses were $3.7 million in the first quarter of 2019, compared to $2.7 million for the same period in 2018. The increase was primarily due to an increase in personnel expenses as a result of an increase in our employee headcount and stock-based compensation expense and an increase in professional and insurance fees.

As of March 31, 2019, Menlo had $121.5 million in cash, cash equivalents and investments, compared to $136.3 million as of December 31, 2018. In March 2019, Menlo issued 358,614 shares of its common stock pursuant to its at-the-market program at an average price of $8.08 per share and received aggregate net proceeds of $2.9 million after deducting sales agent fees. In April 2019, the Company issued 244,316 shares of its common stock pursuant to the at-the-market program at an average price of $7.83 per share resulting in net proceeds to the Company of $1.8 million and total year-to-date aggregate net proceeds under the at-the-market program of $4.7 million.

Updated Cash Runway Guidance

Menlo expects that its current cash, cash equivalents and investments will enable the company to fund its anticipated operating expenses and capital expenditure requirements through the end of 2020.

About Menlo Therapeutics

Menlo Therapeutics Inc. is a late-stage biopharmaceutical company focused on the development of serlopitant, a once-daily oral NK_1 receptor antagonist, for the treatment of pruritus. The company's clinical development program for serlopitant includes two ongoing Phase 3 clinical trials for the treatment of pruritus associated with prurigo nodularis, a planned Phase 3 program for the treatment of pruritus associated with psoriasis, and an ongoing Phase 2 clinical trial for the treatment of chronic pruritus of unknown origin.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Menlo Therapeutics, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including, but not limited to, statements regarding the potential safety and efficacy of serlopitant for the treatment of various conditions, expectations with respect to the timing of enrollment and the anticipated announcement of results of its clinical trials for pruritus associated with prurigo nodularis, psoriasis, and chronic pruritus of unknown origin, the timing of potential regulatory filings, the regulatory process and regulatory approvals and the potential utility of Breakthrough Therapy designation. Such forward-looking statements involve substantial risk and uncertainties that could cause Menlo Therapeutics' development program for serlopitant, future financial results, achievements or performance

to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks that the timing of results, enrollment or commencement of clinical trials may be delayed, the risk that subsequent trials are unsuccessful, despite prior successfully completed clinical trials or do not demonstrate efficacy of serlopitant in the studied indications, the risk of adverse safety events, risks that the costs of clinical trials will exceed expectations, risks resulting from the unpredictability of the regulatory process and regulatory developments in the United States and foreign countries, risks relating to ongoing securities class action litigation, and risks that Menlo Therapeutics will need to raise additional capital and will be unable to do so on favorable terms or at all. These factors, together with those that are described in greater detail in Menlo Therapeutics' Quarterly Report on Form 10-Q to filed on May 2, 2019, as well as any reports that it may file with the SEC in the future, may cause Menlo Therapeutics' actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. Menlo Therapeutics undertakes no obligation to update or revise any forward-looking statements.

- See attached financial tables –

Menlo Therapeutics Inc.
Condensed Statements of Operations
(In thousands, except share per share data, unaudited)

	Three Months Ended March 31,	
	2019	2018
Collaboration and license revenue	$ -	$ 497
Operating expenses:		
Research and development	15,923	11,020
General and administrative	3,746	2,697
Loss from operations	(19,669)	(13,220)
Interest income and other expense, net	796	563
Net loss	$ (18,873)	$ (12,657)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.81)	$ (0.72)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	23,286,282	17,583,377

Menlo Therapeutics Inc.
Condensed Balance Sheet Data
(In thousands)

	March 31, 2019 (unaudited)	December 31, 2018 (1)
Cash, cash equivalents and investments	$ 121,516	$ 136,250
Working capital	114,595	129,956
Total assets	126,258	139,928
Stockholders' equity	115,631	130,377

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Media Contact: media@menlotx.com

Investor Contact: dsheel@menlotx.com