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)
August 1, 2018

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. ☒

Item 2.02. Results of Operations and Financial Condition.

On August 1, 2018, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. The press release is being furnished as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release dated August 1, 2018

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: August 1, 2018

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

Exhibit 99.1

Menlo Therapeutics Reports Second Quarter 2018 Financial Results and Provides Business Update

~ Phase 2 Data in Refractory Chronic Cough Expected in October 2018 ~
~ Phase 2 Data in Psoriasis Expected December 2018 or January 2019 ~
~ New Phase 2 Study in Chronic Pruritus of Unknown Origin Expected to Start in Q4 2018 ~

REDWOOD CITY, Calif., August 1, 2018 -- Menlo Therapeutics Inc. (NASDAQ: MNLO), a late-stage biopharmaceutical company focused on the development of serlopitant for the treatment of pruritus associated with various conditions and for refractory chronic cough, today announced financial results for the second quarter ended June 30, 2018 and provided an update on its clinical development programs.

"We are expanding the serlopitant clinical development program to include a Phase 2 study in chronic pruritus of unknown origin, which we plan to initiate in the fourth quarter. After our recently completed Phase 2 study for the treatment of pruritus in atopic dermatitis patients, we conducted retrospective analyses of our three completed Phase 2 studies of serlopitant in pruritus to provide more insight. As a result of these analyses and discussions with experts in pruritus, we plan to begin a Phase 2 study in patients with chronic pruritus of unknown origin, a significant population that is gaining increasing awareness in the medical community," stated Steve Basta, Chief Executive Officer of Menlo Therapeutics. "Our Phase 2 study in refractory chronic cough enrolled quickly, and we look forward to the results from that study in October. Our Phase 2 study in pruritus associated with psoriasis is nearly fully enrolled, and results are expected in December or January."

Second Quarter Business Highlights and Recent Developments

- In June, Menlo and Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd. (together referred to as "JT Torii") agreed to terminate their License and Collaboration Agreement, dated as of August 10, 2016, for the development and commercialization of products containing serlopitant in Japan. As a result, Menlo now has reacquired full ownership of the development and commercialization rights to serlopitant in Japan.

- In May, Menlo announced a realignment of roles with the promotion of a key member of the clinical development team. Mary Spellman, M.D., a board-certified dermatologist who served as Menlo's Senior Vice President, Clinical Development for the previous year, has been promoted to Chief Medical Officer and will manage the planning and execution of late-stage clinical programs for serlopitant. Paul Kwon, M.D., a board-certified dermatologist, and Menlo's Chief Medical Officer for the previous two years is now Menlo's Chief Scientific Officer. Dr. Kwon is now responsible for leading the scientific strategy of the serlopitant clinical program, exploring potential new indications and overseeing early stage clinical trials of serlopitant to support the anticipated new drug application.

Clinical Program Updates

Pruritus

- Prurigo Nodularis
    - In May, Menlo began enrollment in the first of two Phase 3 studies in pruritus associated with prurigo nodularis in the U.S. and expects to begin enrollment in the second study in Europe in the third quarter of 2018. The company expects to enroll approximately 200 patients with prurigo nodularis in each study.
    - Menlo is currently enrolling a 52-week, multicenter, open-label safety study of serlopitant for the treatment of pruritus. The objective of this study is to provide long-term safety data for serlopitant in adults with pruritus associated with prurigo nodularis, atopic dermatitis, or psoriasis.

- Psoriasis
    - Menlo's Phase 2 study in pruritus associated with psoriasis is approximately 90% enrolled, and the Company expects to report top-line data in December 2018 or January 2019. This trial is limited to patients with psoriasis lesions covering no more than 10% of their body surface area.

- Chronic Pruritus of Unknown Origin

- Based on recent retrospective analyses of Menlo's previously completed Phase 2 clinical trials of serlopitant for the treatment of pruritus, Menlo plans to initiate a Phase 2 study in approximately 200 patients with chronic pruritus of unknown origin in the fourth quarter of 2018.
- Menlo's recent retrospective analyses showed trends that suggest patients without inflammatory skin disease, older patients or patients who had been pruritic for longer, appeared to respond better to serlopitant therapy than patients with inflammatory skin disease, who were younger or had a shorter duration of pruritus.

- Atopic Dermatitis
  - In April, Menlo announced top-line results from the Phase 2 clinical trial of serlopitant for the treatment of pruritus in adults and adolescents with a history of atopic dermatitis. The study did not meet its primary or key secondary efficacy endpoints with no statistically significant difference demonstrated between the serlopitant treated groups and the placebo treated group. Numerical differences favoring the serlopitant treated groups were evident at all timepoints. Serlopitant was well-tolerated in this study.

Refractory Chronic Cough

- Menlo has completed the enrollment (185 patients) of its Phase 2 study in patients with refractory chronic cough and expects to report top-line data in October of 2018.

Financial Results

Second Quarter 2018 Financial Results

Menlo reported a net loss attributable to common stockholders of $8.3 million, or $0.36 per share for the second quarter of 2018, compared to a net loss of $6.2 million, or $1.21 per share for the same period in 2017.

Collaboration and license revenue for the second quarter of 2018 was $10.1 million, compared to $0.4 million for the same period in 2017. The increase in collaboration and license revenue is primarily related to the accelerated recognition of the initial upfront payment resulting from the termination of the JT Torii Collaboration Agreement in the second quarter of 2018 and a $2.0 million milestone payment pursuant to the Collaboration Agreement prior to its termination.

Research and development expenses for the second quarter of 2018 were $16.2 million, compared to $5.5 million for the same period in 2017. The increase was primarily due to an increase in clinical trial expenses and a $3.0 million milestone payment to Merck associated with the initiation of Menlo's Phase 3 clinical trial for pruritus associated with prurigo nodularis.

General and administrative expenses for the second quarter of 2018 were $3.1 million, compared to $1.2 million for the same period in 2017. The increase was primarily due to higher personnel-related expenses to support Menlo's expanding operations.

As of June 30, 2018, Menlo had $164.2 million in cash, cash equivalents and investments, compared to $62.5 million as of December 31, 2017.

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 associated with various conditions and for refractory chronic cough. The Company's clinical development program for serlopitant includes ongoing and planned Phase 3 studies for the treatment of pruritus associated with prurigo nodularis, ongoing Phase 2 studies for the treatment of pruritus associated with psoriasis and refractory chronic cough, and a planned Phase 2 study 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 timing of the anticipated announcement of results of Phase 2 clinical studies for pruritus associated with psoriasis and for refractory chronic cough, expectations about the start and conduct of a Phase 2 trial for chronic pruritus of unknown origin and a Phase 3 clinical trial in Europe for pruritus associated with prurigo nodularis. Such forward-looking statements involve substantial risk and uncertainties that could cause Menlo Therapeutics' development program for serlopitant, future 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 do not replicate the results from 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 that Menlo Therapeutics will need to raise additional capital and will be unable to do so on favorable terms or at all, risks of competition and the risk that Menlo Therapeutics is not able to successfully defend or protect its intellectual property. These factors, together with those that are described in greater detail in Menlo Therapeutics Annual Report on Form 10-K filed on March 28, 2018 and its Quarterly Report on Form 10-Q that it expects to file on August 1, 2018, 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 per share data, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration and license revenue	$ 10,143	$ 449	$ 10,640	$ 898
Operating expenses:				
Research and development	16,226	5,460	27,246	10,452
General and administrative	3,090	1,214	5,787	2,226
Loss from operations	(9,173)	(6,225)	(22,393)	(10,780)
Interest income and other expense, net	826	72	1,388	153
Net loss	$ (8,347)	$ (6,153)	$ (21,005)	$ (11,627)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (1.21)	$ (1.04)	$ (2.29)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	22,872,196	5,092,331	20,242,341	5,082,026

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

	June 30, 2018 (unaudited)	December 31, 2017 (1)
Cash, cash equivalents and investments	$ 164,180	$ 62,479
Working capital	147,514	56,044
Total assets	166,916	66,867
Stockholders' equity (deficit)	158,189	(57,034)

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Media Contact: media@menlotx.com

Investor Contact: dsheel@menlotx.com