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)
December 10, 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 7.01 Regulation FD Disclosure.

On December 10, 2018, Menlo Therapeutics Inc. issued a press release announcing the results of its Phase 2 clinical trial of serlopitant for the treatment of psoriasis. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Security Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release dated December 10, 2018

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.

Menlo Therapeutics, Inc.

/s/ Steven Basta
Steven Basta
Chief Executive Officer

Date: December 10, 2018

Exhibit 99.1

Menlo Therapeutics' Successful Phase 2 Clinical Trial of Serlopitant Demonstrates Reduction of Pruritus Associated with Psoriasis

Company to Conduct Conference Call and Webcast Today at 8:00am ET / 5:00am PT

REDWOOD CITY, Calif., December 10, 2018 -- Menlo Therapeutics Inc. (NASDAQ: MNLO), a late-stage biopharmaceutical company focused on the development of serlopitant for the treatment of pruritus (itch), today announced positive top-line results from MTI-109 (PSORIXA), a 204-patient Phase 2 clinical trial of serlopitant for the treatment of pruritus associated with psoriasis. The trial successfully met its primary endpoint, showing a statistically significant reduction in pruritus based upon a 4-point improvement responder analysis. In the trial, 33% of patients treated with serlopitant 5 mg daily achieved a 4-point or greater improvement on the worst-itch numeric rating scale, or WI-NRS, at week 8 compared to baseline (primary efficacy endpoint) vs. 21% of patients treated with placebo ($p= 0.028$).

The trial also prospectively defined three key secondary endpoints for sequential step-down analyses at week 4 and days 7 and 3. The trial successfully met the secondary endpoint of WI-NRS responder rate at week 4. At week 4, 21% of patients treated with serlopitant achieved a 4-point or greater improvement on the WI-NRS vs. 11% of patients treated with placebo ($p=0.039$). Assessment of the secondary endpoints of the absolute change in WI-NRS from baseline to day 7 and day 3 for serlopitant compared to placebo showed a greater numerical, but not statistically significant, improvement for the serlopitant group. At every assessed time point in the trial (daily in week 1 and average weekly scores through week 8), the serlopitant treated group demonstrated greater numerical improvement than the placebo group in both the WI-NRS 4-point responder analysis and in the mean change in WI-NRS from baseline.

Serlopitant was well-tolerated in this clinical trial. No serious adverse events were reported for serlopitant treated patients. Treatment-emergent adverse events assessed as likely related to treatment were observed with similar frequency in both groups (4.0% for placebo and 4.9% for serlopitant). The consolidated safety summary for serlopitant now includes more than 1,600 evaluable patients, including patients who have received treatment for up to one year.

"We are pleased with the positive results demonstrated by serlopitant in this clinical trial for the treatment of pruritus associated with psoriasis. We have now completed four double-blind Phase 2 clinical trials in over 1,000 patients with pruritus and met the primary endpoint in three of the four trials. In all four of these trials, all serlopitant treated groups have shown numerically greater improvement from baseline as compared to placebo treated groups at every assessed timepoint," stated Steve Basta, Chief Executive Officer of Menlo Therapeutics. "We plan to have an End of Phase 2 Meeting with the FDA in the first half of 2019 and to begin our Phase 3 program for pruritus associated with psoriasis in 2019."

MTI-109 was a randomized, double-blind, placebo-controlled clinical trial which evaluated the efficacy, safety, and tolerability of serlopitant for the treatment of pruritus associated with psoriasis. The trial enrolled patients between 18 and 80 years of age with the diagnosis of plaque psoriasis for at least 6 months prior to randomization and with plaques covering $\leq$ 10% body surface area. In addition, patients had pruritus of at least 4 weeks duration prior to screening and a WI-NRS score consistent with severe pruritus at screening. Patients were randomized 1:1 to receive either serlopitant 5 mg or placebo orally once daily and were not allowed to use any other psoriasis therapy, other than bland emollients, for the duration of the trial. MTI-109 was intended to evaluate if treatment with serlopitant 5 mg daily for 8 weeks could improve pruritus compared with placebo. The primary efficacy endpoint was a responder analysis of the proportion of patients in each group achieving a 4-point WI-NRS improvement at week 8

compared to baseline. As a randomized Phase 2 trial, the pre-defined statistical threshold for significance was a p-value of < 0.05 (one-sided test).

Update on Serlopitant Clinical Development Program

- **Prurigo Nodularis:** 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 prurigo nodularis. The U.S. trial is over 50% enrolled, and the European trial is over 30% enrolled. Data from each trial is expected by the first quarter of 2020.
- **Psoriasis**: Menlo plans to have an End of Phase 2 Meeting with the FDA in the first half of 2019 and expects to initiate a Phase 3 program in 2019 to evaluate serlopitant as a treatment for pruritus associated with psoriasis.
- **Chronic Pruritus of Unknown Origin**: Menlo is currently screening patients for its Phase 2 clinical trial in patients with chronic pruritus of unknown origin and expects to enroll the first patient in this Phase 2 trial in December 2018 or January 2019.

Conference Call and Webcast

Management will conduct a conference all at 8:00am ET / 5:00am PT today, Monday December 10, 2018 to discuss the results. The conference call will be webcast live and can be accessed by logging on to the "Investors" section of the Menlo Therapeutics website, www.menlotherapeutics.com, prior to the event. A replay of the webcast will be archived on the Company's website for 30 days following the call.

To participate on the live call, please dial (877) 253-4330 (toll-free) or (706) 643-0896 (toll) and reference conference ID 4633289 prior to the start of the call.

About Psoriasis

Psoriasis is a common chronic autoimmune disorder of the skin, causing redness, irritation and scaly lesions. Approximately 12 million people in the United States have psoriasis, of which, according to the National Psoriasis Foundation, approximately 75% have mild psoriasis and 25% have moderate to severe psoriasis. According to market research conducted by Menlo, approximately 75% of psoriasis patients have moderate to severe pruritus.

About Serlopitant

Serlopitant is a once-daily NK_1 receptor antagonist being developed for the treatment of pruritus, or itch, associated with various conditions such as prurigo nodularis, psoriasis and chronic pruritus of unknown origin. Menlo has completed three Phase 2 clinical trials with serlopitant showing a statistically significant reduction in pruritus compared to placebo. Serlopitant has been evaluated in over 1,600 patients and has been shown to be well-tolerated, including in patients who have received treatment for up to one year. Serlopitant is an investigational drug that is not currently approved for use in any indication.

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 a 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 expectations about the Company's ability to develop and advance product candidates into and successfully complete clinical trials, the efficacy and safety of serlopitant, the enrollment and timing of data related to two active Phase 3 clinical trials for pruritus associated with prurigo nodularis, the timing of an end of Phase 2 meeting with the FDA, the timing of the initiation of a Phase 3 program in psoriasis, and the timing of enrollment of the first patient in its Phase 2 trial of patients with chronic pruritus of unknown origin. 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, the risk associated with the unpredictability of the regulatory process and regulatory developments in the United States and foreign countries, 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 filed on November 7, 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.

Media Contact: media@menlotx.com

Investor Contact: dsheel@menlotx.com