# 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)**
**October 8, 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 8.01 Other Events.**

On October 8, 2018, Menlo Therapeutics Inc. issued a press release announcing the results of its Phase 2 clinical trial of serlopitant for the treatment of refractory chronic cough. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 8.01, 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 October 8, 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: October 9, 2018

**Exhibit 99.1**

**Menlo Therapeutics Announces Results from a Phase 2 Clinical Trial of Serlopitant for the Treatment of Refractory Chronic Cough**

***Serlopitant fails to demonstrate efficacy relative to placebo on primary and secondary endpoints***

REDWOOD CITY, Calif., October 8, 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, today announced top-line results from MTI-110 (TUSSIX), its Phase 2 clinical trial of serlopitant for the treatment of refractory chronic cough. In this 185 patient study, treatment with serlopitant failed to demonstrate benefit versus placebo on the primary and key secondary endpoints. In the primary endpoint analysis of change from baseline in 24-hour cough frequency after 12 weeks of treatment, the serlopitant group had 31% less reduction than the placebo group. In a key secondary analysis of response rates, 54% of placebo treated patients and 44% of serlopitant treated patients experienced a 30% or greater reduction in 24-hour cough frequency at week 12 compared to baseline. Serlopitant was well-tolerated in this study. Treatment related adverse events occurred at comparable rates in the serlopitant and placebo treated groups.

“Based upon the results of this trial, we do not anticipate further development of serlopitant for the treatment of refractory chronic cough. We sincerely thank the patients and investigators who participated in this trial,” stated Steve Basta, CEO of Menlo Therapeutics. “We are continuing the clinical development of serlopitant for pruritus associated with various conditions given the two successful Phase 2 clinical trials in which serlopitant demonstrated a reduction in chronic pruritus and pruritus associated with prurigo nodularis.”

**Update on Serlopitant Clinical Development in Pruritus**

- The Phase 2 clinical trial of serlopitant to treat pruritus associated with psoriasis is fully enrolled, and data is expected in December 2018.
- We are 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. Data from each trial is expected in the first half of 2020.
- We plan to initiate a Phase 2 clinical trial in patients with chronic pruritus of unknown origin this year and expect results in the first half of 2020.

**About Serlopitant**

Serlopitant is a once-daily $NK_1$ receptor antagonist being developed for the treatment of pruritus, or itch, associated with various conditions. Menlo Therapeutics has completed two Phase 2 studies with serlopitant showing a statistically significant reduction in pruritus compared to placebo. Originally developed by Merck and licensed to Menlo Therapeutics in 2012, serlopitant has been evaluated in approximately 1,500 patients and has been shown to be well-tolerated, including in patients who have received treatment for up to a 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 associated with various

conditions. The Company's clinical development program for serlopitant includes ongoing Phase 3 studies for the treatment of pruritus associated with prurigo nodularis, an ongoing Phase 2 study for the treatment of pruritus associated with psoriasis, 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 expectations about the timing of data related to the Phase 2 clinical trial of serlopitant to treat pruritus associated with psoriasis, the conduct of the two active Phase 3 clinical trials for pruritus associated with prurigo nodularis and the conduct of an anticipated Phase 2 trial in 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, 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 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.

Media Contact: media@menlotx.com

Investor Contact: dsheel@menlotx.com