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 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 7.01. Regulation FD Disclosure.

On April 8, 2018, Menlo Therapeutics, Inc. issued a press release announcing the results of its Phase 2 study of serlopitant as a treatment for pruritus associated with atopic dermatitis. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Current Report on Form 8-K and the exhibit attached hereto shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to 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, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release dated April 8, 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: April 9, 2018

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

Menlo Therapeutics Announces Results from a Phase 2 Trial of Serlopitant for Pruritus Associated with Atopic Dermatitis

Company to Host Conference Call Monday April 9 at 4:00am PT / 7:00am ET

REDWOOD CITY, Calif., April 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 underlying dermatologic conditions and for the treatment of refractory chronic cough, today announced top-line results from MTI-103 (ATOMIK), the Phase 2 clinical trial of serlopitant for the treatment of pruritus in adults and adolescents with a history of atopic dermatitis (AD). 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 group were evident at all timepoints. Serlopitant was well-tolerated in this study.

Summary Results:

Endpoint	Placebo	Serlopitant 1 mg		Serlopitant 5 mg	
Mean Change from Baseline					
	Absolute Change	**Absolute Change**	**Treatment Effect[(1)]**	**Absolute Change**	**Treatment Effect[(1)]**
WI-NRS mean change from baseline at week 2	-1.13	-1.42	-0.29	-1.29	-0.16
WI-NRS mean change from baseline at week 4	-1.66	-1.79	-0.13	-1.78	-0.12
WI-NRS change mean from baseline at week 6 (Primary Endpoint)	-2.01	-2.32	-0.32 (p=0.11)	-2.25	
Responder Rate Analysis					
	Response Rate	**Response Rate**	**Treatment Effect[(2)]**	**Response Rate**	**Treatment Effect[(2)]**
WI-NRS ≥ 4-point responder rate at week 6 (Secondary Endpoint)	16.5%	22.4%	5.9% (p=0.09)	20.6%	4.2% (p=0.17)

(1) Treatment effect represents the difference between the absolute change in the serlopitant treated groups vs. the absolute change in the placebo treated group.

(2) Treatment effect represents the difference between the response rate in the serlopitant treated groups vs. the response rate in the placebo treated group.

“While we are disappointed that the results in this Phase 2 trial of pruritus associated with atopic dermatitis did not reach statistical significance and did not show the same magnitude of treatment effect as in our prior pruritus studies, we do see in the results a pattern that shows numerical improvement in each serlopitant treatment group above the placebo group at every timepoint. This is our third pruritus study of serlopitant. Reduction of pruritus has been demonstrated in two prior Phase 2 studies, one trial in patients with chronic pruritus and one trial in patients with prurigo nodularis,” stated Steve Basta, Chief Executive Officer of Menlo Therapeutics. “We are initiating Phase 3 studies in prurigo nodularis

this quarter, and we are looking forward to the Phase 2 results in refractory chronic cough in the fourth quarter of this year, and the Phase 2 results in pruritus associated with psoriasis by late 2018 or early 2019."

Serlopitant was well-tolerated in this study. No serious adverse events were assessed as likely related to serlopitant. Treatment-emergent adverse events that were assessed as possibly related to treatment were observed with similar frequency in all three study groups (9.5% for placebo, 7.5% for 1 mg, and 8.1% for 5 mg). The only treatment emergent adverse events that were reported in more than 5% of patients in any study group were worsening of atopic dermatitis (3.2% for placebo, 1.3% for 1 mg, and 5.6% for 5 mg) and worsening of pruritus (5.1% for placebo, 5.6% for 1 mg, and 1.9% for 5 mg). The consolidated safety summary for serlopitant now includes more than 1,300 patients that have been evaluated, including patients who have received treatment for up to a year.

The ATOMIK, MTI-103 study, was a multi-center, randomized, placebo-controlled Phase 2 clinical trial conducted at 52 US sites to assess the efficacy, safety and tolerability of serlopitant. The study enrolled 484 subjects ages 13 years of age and older with a past or present diagnosis of atopic dermatitis, pruritus for at least six weeks, and an average weekly WI-NRS score ≥ 6 for each of the two weeks of the screening period, as recorded in the eDiary. Patients were randomized into one of three treatment arms: once-daily doses of placebo, 1 mg serlopitant, or 5 mg serlopitant. The trial included a two-week screening period, a six-week treatment period and a four-week follow-up period. This trial was intended to evaluate if treatment with either 5 mg or 1 mg serlopitant daily for six weeks could reduce pruritus associated with atopic dermatitis compared with placebo. The primary efficacy analysis compared the difference between serlopitant and placebo in the mean change in WI-NRS from baseline to week 6. A key secondary endpoint was a responder-rate analysis of a 4-point WI-NRS improvement at week 6.

Management will conduct a conference all at 4:00AM PT / 7: 00AM ET on Monday April 9, 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 6191407 prior to the start of the call.

About Serlopitant

Serlopitant is a once-daily NK_1 receptor antagonist being developed for the treatment of pruritus, or itch, associated with atopic dermatitis, psoriasis, and prurigo nodularis. Serlopitant is also being evaluated as a potential treatment for refractory chronic cough, a cough which persists for greater than eight weeks despite treatment of any identified underlying cause. Menlo Therapeutics has completed three Phase 2 studies with serlopitant showing a statistically significant reduction in pruritus compared to placebo in two of the three studies. Originally developed by Merck and licensed to Menlo Therapeutics in 2012, serlopitant has been evaluated in more than 1,300 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 underlying dermatologic conditions and for refractory chronic cough. The Company has a broad clinical

development program for serlopitant including two ongoing Phase 2 studies for the treatment of pruritus associated with psoriasis and refractory chronic cough and expects to start Phase 3 trials for the treatment of pruritus associated with prurigo nodularis in the second quarter of 2018. Menlo Therapeutics has exclusive worldwide rights to serlopitant, excluding in Japan where Menlo Therapeutics has licensed exclusive rights to JT Torii.

Forward Looking Statements

This press release contains forward-looking statements, including but not limited to the potential of serlopitant to treat pruritus associated with atopic dermatitis, psoriasis, and prurigo nodularis, or to treat refractory chronic cough, the anticipated announcement of results of Phase 2 clinical studies for refractory chronic cough and pruritus associated with psoriasis, and expectations about the start of Phase 3 clinical trials 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 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, risks of competition and the risk that Menlo Therapeutics is not able to successfully defend or protect its intellectual property. For more information about these and other risks, see Menlo Therapeutics' annual report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2018, under the heading "Risk Factors" and any subsequent current and periodic reports filed with the Securities and Exchange Commission. Menlo Therapeutics undertakes no obligation to update these forward-looking statements.

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