# 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)**
**February 27, 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. ☒

**Item 2.02. Results of Operations and Financial Condition.**

On February 27, 2019, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2018. 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 February 27, 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: February 27, 2019

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

**Exhibit 99.1**

**Menlo Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results**

REDWOOD CITY, Calif., February 27, 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 fourth quarter and year ended December 31, 2018 and provided an update on its clinical development programs.

"We are making solid progress in the clinical development of serlopitant for pruritus associated with prurigo nodularis (PN), our most advanced indication. Both Phase 3 PN trials are enrolling well, and we expect results from these trials in the first half of 2020," stated Steve Basta, Chief Executive Officer of Menlo Therapeutics. "If our PN trials are successful, we expect to file an NDA for our first indication in 2020. The FDA recently granted serlopitant Breakthrough Therapy designation for pruritus associated with PN, which reflects the unmet need in this indication and the positive results from our Phase 2 clinical trial of serlopitant for the treatment of itch associated with PN."

**Clinical Program Updates**

Prurigo Nodularis

- On January 15, 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 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. Results from these trials are expected in the first half of 2020.
    - At least 130 patients have been enrolled in each of the Phase 3 trials to date.
    - Menlo intends to increase the target number of patients for each of the PN Phase 3 trials from 200 patients to approximately 280 patients in consideration of data from all of our completed Phase 2 pruritus trials, including the recently completed psoriasis trial. Increasing the number of patients in each trial may enable statistical significance to be achieved in a greater range of trial outcomes.
- Menlo is also currently enrolling patients in a 52-week, multicenter, open-label safety study of serlopitant for the treatment of pruritus associated with prurigo nodularis, 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 200 patients have been enrolled in this open-label study to date.

Psoriasis

- On December 10, 2018, Menlo announced that the Phase 2 clinical trial of serlopitant for the treatment of pruritus associated with psoriasis met its primary endpoint, showing a statistically significant reduction in pruritus based upon a 4-point improvement responder analysis. In this 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 company expects to have an End of Phase 2 Meeting with the FDA in the first half of 2019 and to begin a Phase 3 program for pruritus associated with psoriasis in 2019.
- The results of the recently completed Phase 2 trial in patients with pruritus associated with psoriasis will be presented on March 2, 2019 at the Annual Meeting of the American Academy of Dermatology.

Chronic Pruritus of Unknown Origin

- Menlo is conducting a Phase 2 clinical trial in patients with chronic pruritus of unknown origin. The company 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**

*Fourth Quarter 2018 Financial Results*

Menlo reported a net loss attributable to common stockholders of $17.6 million for the fourth quarter of 2018, compared to a net loss of $9.3 million for the same period in 2017.

Collaboration and license revenue was zero in the fourth quarter of 2018 compared to $2.8 million for the same period in 2017. 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 $15.1 million in the fourth quarter of 2018, compared to $10.5 million for the same period in 2017. The increase was primarily due to an increase in clinical trial expenses, an increase in personnel expenses and stock-based compensation expense as a result of an increase in our employee headcount, and an increase in manufacturing expenses.

General and administrative expenses were $3.4 million in the fourth quarter of 2018, compared to $1.7 million for the same period in 2017. The increase was primarily due to an increase in professional fees as a result of becoming a public company as well as an increase in personnel expenses and stock-based compensation expense as a result of an increase in our employee headcount.

*Full Year 2018 Financial Results*

Menlo reported a net loss attributable to common stockholders of $51.4 million for the year ended December 31, 2018, compared to a net loss of $29.1 million for the year ended December 31, 2017.

Collaboration and license revenue was $10.6 million for the year ended December 31, 2018 compared to $4.6 million for the same period in 2017. The increase was primarily due 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 were $53.0 million for the year ended December 31, 2018 compared to $29.0 million for the same period in 2017. The increase was primarily due to an increase in clinical trial expenses, an increase in personnel expenses and stock-based compensation expense as a result of an increase in our employee headcount, and an increase in manufacturing expenses. In addition, in May 2018, we made a $3.0 million milestone payment to Merck associated with the initiation of our Phase 3 clinical trials for pruritus associated with prurigo nodularis.

General and administrative expenses were $12.2 million for the year ended December 31, 2018, compared to $5.2 million for the same period in 2017. The increase was primarily due to increases in professional fees as a result of becoming a public company as well as an increase in personnel expenses and stock-based compensation expense as a result of an increase in our employee headcount.

As of December 31, 2018, Menlo had $136.3 million in cash, cash equivalents and investments, compared to $62.5 million as of December 31, 2017.

**Financial Outlook**

Menlo expects that its current cash, cash equivalents and investments will enable the company to fund its anticipated operating expenses and capital expenditure requirements into the fourth quarter of 2020. Menlo expects operating expenses for the full year 2019 to be in the range of $78.0 to $88.0 million, including stock-based compensation of $3.0 to $6.0 million. The 2019 operating expenses will be primarily driven by ongoing development activities related to serlopitant.

**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 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 potential utility of Breakthrough Therapy designation, and expected cash needs and operating expenses for the full year 2019. 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 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 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' Annual Report on Form 10-K to be filed on February 28, 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.**

**Statement of Operations Data**

**(In thousands, except per share data)**

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Collaboration and license revenue | $ - | $ 2,775 | $ 10,640 | $ 4,582 |
| Operating expenses: | | | | |
| Research and development | 15,076 | 10,546 | 52,989 | 29,007 |
| General and administrative | 3,364 | 1,706 | 12,186 | 5,168 |
| Loss from operations | (18,440) | (9,477) | (54,535) | (29,593) |
| Interest income and other expense, net | 846 | 200 | 3,090 | 517 |
| Net loss | $ (17,594) | $ (9,277) | $ (51,445) | $ (29,076) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.76) | $ (1.80) | $ (2.37) | $ (5.69) |
| Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted | 23,166,417 | 5,152,087 | 21,668,689 | 5,108,121 |

**Menlo Therapeutics Inc.**

**Condensed Balance Sheet Data**

**(In thousands)**

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Cash, cash equivalents and investments | $ 136,250 | $ 62,479 |
| Working capital | 129,956 | 56,044 |
| Total assets | 139,928 | 66,867 |
| Stockholders' equity (deficit) | 130,377 | (57,034) |

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