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)
November 7, 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 November 7, 2018, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 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 November 7, 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: November 7, 2018

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

Exhibit 99.1

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

~ Phase 2 Data in Psoriasis Expected December 2018 ~
~ New Phase 2 Clinical Trial in Chronic Pruritus of Unknown Origin Expected to Start in Q4 2018 ~
~ Prurigo Nodularis Phase 3 Clinical Trials Enrolling in U.S. and Europe ~

REDWOOD CITY, Calif., November 7, 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 financial results for the third quarter ended September 30, 2018 and provided an update on its clinical development programs.

Clinical Program Updates

Pruritus

- 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. Data from each trial is expected in the first half of 2020.
  - 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 clinical trial in pruritus associated with psoriasis is fully enrolled, and the Company expects to report top-line data in December 2018. This trial is limited to patients with psoriasis lesions covering no more than 10% of their body surface area.

- Chronic Pruritus of Unknown Origin
  - Menlo plans to initiate a Phase 2 clinical trial in approximately 200 patients with chronic pruritus of unknown origin in the fourth quarter of 2018. This trial follows recent retrospective analyses of Menlo's previously completed Phase 2 clinical trials of serlopitant for the treatment of pruritus, which suggested a potential for greater treatment effect of serlopitant in patients without inflammatory skin disease.

Refractory Chronic Cough

- On October 8, 2018, Menlo announced the results from MTI-110, 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. Treatment related adverse events occurred at comparable rates in the serlopitant and placebo treated groups. Based upon the results of this trial, Menlo does not anticipate further development of serlopitant for the treatment of refractory chronic cough.

Financial Results

Third Quarter 2018 Financial Results
Menlo reported a net loss attributable to common stockholders of $12.8 million, or $0.56 per share for the third quarter of 2018, compared to a net loss of $8.2 million, or $1.60 per share for the same period in 2017.

Collaboration and license revenue for the third quarter of 2018 was zero compared to $0.9 million for the corresponding 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 for the third quarter of 2018 increased to $10.7 from $8.0 million for the corresponding period in 2017. The increase was primarily due to an increase in clinical trial expenses, an increase in personnel expenses as a result of an increase in our employee headcount, and an increase in manufacturing expenses.

General and administrative expenses for the third quarter of 2018 increased to $3.0 million from $1.2 million for the corresponding 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 as a result of an increase in our employee headcount.

As of September 30, 2018, Menlo had $152.7 million in cash, cash equivalents and investments, compared to $62.5 million as of December 31, 2017.

Updated 2018 Operating Expense Guidance

Menlo is lowering operating expense guidance for the full year 2018 to a range of $62.0 to $67.0 million, including approximately $4.0 million in stock-based compensation, from its prior projection of a range of $68.0 to $78.0 million. 2018 operating expenses are primarily driven by development activities related to serlopitant and Menlo's general and administrative infrastructure.

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 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 the timing of the anticipated announcement of results of its Phase 2 clinical trial for pruritus associated with psoriasis, expectations about the start and conduct of a Phase 2 clinical trial for chronic pruritus of unknown origin, the conduct and timing of data from its Phase 3 clinical trials in the United States and Europe for pruritus associated with prurigo nodularis, the objectives for the multicenter, open-label safety study of serlopitant for the treatment of pruritus and expected operating expenses for the full year 2018. 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 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.

- See attached financial tables –

Menlo Therapeutics Inc.
Condensed Statements of Operations
(In thousands, except per share data, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration and license revenue	$ -	$ 909	$ 10,640	$ 1,807
Operating expenses:				
Research and development	10,667	8,008	37,913	18,461
General and administrative	3,035	1,236	8,822	3,462
Loss from operations	(13,702)	(8,335)	(36,095)	(20,116)
Interest income and other expense, net	855	163	2,243	316
Net loss	$ (12,847)	$ (8,172)	$ (33,852)	$ 19,800
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (1.60)	$ (1.60)	$ (3.89)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	22,977,793	5,116,165	21,164,069	5,093,418

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

	September 30, 2018 (unaudited)	December 31, 2017 (1)
Cash, cash equivalents and investments	$ 152,657	$ 62,479
Working capital	146,406	56,044
Total assets	154,958	66,867
Stockholders' equity (deficit)	146,884	(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.

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