
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)
March 28, 2018

Menlo Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38356
(Commission File Number)

45-3757789
(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 March 28, 2018, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2017. 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 March 28, 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

By: Kristine Ball

Senior Vice President, Corporate Strategy and
Chief Financial Officer

Date: March 28, 2018

Menlo Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results

REDWOOD CITY, Calif., March 28, 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 refractory chronic cough, today announced financial results for the fourth quarter and year ended December 31, 2017 and provided an update on its clinical development programs.

“We are extremely pleased with the completion of our initial public offering. The funds from the IPO will provide Menlo the ability to advance the development of serlopitant as a potential once-daily therapy for pruritus and cough. We look forward to seeing the results from our Phase 2 study (ATOMIK) in atopic dermatitis which are expected in April of 2018,” stated Steve Basta, Chief Executive Officer of Menlo Therapeutics.

Fourth Quarter Business Highlights and Recent Developments

- In January, we successfully completed our initial public offering (IPO) of common stock of 8,050,000 shares of common stock at a public offering price of \$17.00 per share, which includes the exercise in full by the underwriters of their over-allotment option. We raised net proceeds of approximately \$125.5 million, after deducting underwriting discounts, commissions and offering expenses.
- In November 2017, we initiated enrollment in a 200-patient Phase 2 clinical trial evaluating serlopitant for the treatment of pruritus associated with psoriasis.
- In October 2017, we initiated enrollment in a 170-patient Phase 2 trial evaluating serlopitant as a treatment for refractory chronic cough.
- During 2017, we expanded our management team with key hires in finance, clinical development, medical affairs and commercial development.

Clinical Program Updates

Atopic Dermatitis

- We have completed the treatment and follow-up period for all patients in our Phase 2 study of serlopitant as a treatment for pruritus associated with atopic dermatitis, and expect to report data from this study in April 2018.

Psoriasis

- We expect to report data from our ongoing Phase 2 study in pruritus associated with psoriasis in late 2018 or early 2019 as previously indicated.
-

Prurigo Nodularis

- We plan to initiate two Phase 3 studies in pruritus associated with prurigo nodularis in the second quarter of 2018. We expect to enroll approximately 200 patients in each study. One study will be conducted in the U.S. and one in Europe.
- We have recently started 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.

Refractory Chronic Cough

- We are updating timing for data from our Phase 2 study in refractory chronic cough. We now expect to report data from this study in the fourth quarter of 2018 versus our prior guidance of late 2018 or early 2019.

Financial Results

Fourth Quarter 2017 Financial Results

Menlo reported a net loss attributable to common stockholders of \$9.3 million for the fourth quarter of 2017, compared to a net loss of \$4.8 million for the same period in 2016.

Collaboration and license revenue was \$2.8 million in the fourth quarter of 2017 compared to \$0.5 million for the same period in 2016. The increase was primarily due to \$2.0 million in milestone revenue recognized under the Company's August 2016 License and Collaboration Agreement with Japan Tobacco Inc./Torii Pharmaceutical (JT Torii).

Research and development expenses were \$10.5 million in the fourth quarter of 2017, compared to \$4.1 million for the same period in 2016. The increase was primarily due to an increase in clinical trial expenses related to the development of serlopitant and higher personnel-related expenses.

General and administrative expenses were \$1.7 million in the fourth quarter of 2017, compared to \$1.3 million for the same period in 2016. The increase was primarily due to higher personnel-related expenses to support our expanding operations.

Full Year 2017 Financial Results

Menlo reported a net loss attributable to common stockholders of \$29.1 million for the year ended December 31, 2017, compared to a net loss of \$14.1 million for the year ended December 31, 2016.

Collaboration and license revenue was \$4.6 million for the year ended December 31, 2017 compared to \$0.7 million for the same period in 2016. The increase was primarily due to a full year's amortization of revenue from

the initial upfront payment under the collaboration agreement with JT Torii and \$2.0 million in milestone revenue from JT Torii.

Research and development expenses were \$29.0 million for the year ended December 31, 2017 compared to \$11.3 million for the same period in 2016. The increase was primarily due to an increase in clinical trial expenses related to the development of serlopitant and higher personnel-related expenses.

General and administrative expenses were \$5.2 million for the year ended December 31, 2017 compared to \$3.8 million for the same period in 2016. The increase was primarily due to increases in personnel-related expenses to support our expanding operations.

As of December 31, 2017, Menlo had \$62.5 million in cash, cash equivalents and investments, compared to \$41.3 million as of December 31, 2016. In January 2018 the company completed the initial public offering of its common stock resulting in net proceeds of approximately \$125.5 million. Shares outstanding immediately after the initial public offering were approximately 23.0 million, which includes common stock issued during the initial public offering and the conversion of convertible preferred stock into shares of common stock at the time of the initial public offering.

Financial Outlook

For the full year 2018, Menlo expects operating expenses in the range of approximately \$77.0 to \$87.0 million, including stock-based compensation of approximately \$3.0 to \$6.0 million. The 2018 operating expenses will be primarily driven by ongoing development activities related to serlopitant and increases in the company'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 associated with various underlying dermatologic conditions and for refractory chronic cough. The Company has initiated a broad clinical development program for serlopitant including Phase 2 studies for the treatment of pruritus associated with atopic dermatitis, 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 conduct and anticipated announcement of results of Phase 2 clinical studies for pruritus associated with atopic dermatitis, refractory chronic cough and psoriasis, expectations about the start of Phase 3 clinical trials for pruritus associated with prurigo nodularis, 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 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' Form S-1/A filed with the Securities and Exchange Commission on January 23, 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.

- See attached financial tables -

Menlo Therapeutics Inc.
Statement of Operations Data
(In thousands, except per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
	(Unaudited)			
Collaboration and license revenue	\$ 2,775	\$ 450	\$ 4,582	\$ 674
Operating expenses:				
Research and development	10,546	4,078	29,007	11,255
General and administrative	1,706	1,296	5,168	3,751
Loss from operations	(9,477)	(4,924)	(29,593)	(14,332)
Interest income and other expense, net	200	88	517	264
Net loss	\$ (9,277)	\$ (4,836)	\$ (29,076)	\$ (14,068)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.80)	\$ (0.96)	\$ (5.69)	\$ (2.82)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	5,152,087	5,051,111	5,108,121	4,987,133

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

	December 31,	
	2017	2016
Cash, cash equivalents and investments	\$ 62,479	\$ 41,328
Working capital	56,044	27,637
Total assets	66,867	42,053
Stockholders' deficit	(57,034)	(29,441)

Media Contact: media@menlotx.com

Investor Contact: dsheel@menlotx.com