
**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): January 22, 2024

SEMLER SCIENTIFIC, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36305
(Commission File Number)

26-1367393
(IRS Employer Identification No.)

2340-2348 Walsh Avenue, Suite 2344
Santa Clara, CA
(Address of principal executive offices)

95051
(Zip Code)

Registrant's telephone number, including area code: **(877) 774-4211**

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 (*see* General Instruction A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	SMLR	The Nasdaq Stock Market LLC

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 Information

Semler Scientific, Inc., or Semler, will seek a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the expanded use of QuantaFlo® following correspondence with the FDA.

The new 510(k) is intended to enable expanded labeling for QuantaFlo® as an aid in the diagnosis of other cardiovascular diseases in addition to peripheral artery disease, or PAD.

Semler will continue to market and sell QuantaFlo® as an aid in the diagnosis of PAD, which is responsible for over 99% of its historical revenue to date. The roll-out of QuantaFlo® as aid in the diagnosis of other cardiovascular diseases is subject to FDA clearance of the new 510(k) clearance.

Forward-Looking Statements

This current report contains “forward-looking” statements. Such statements can be identified by, among other things, the use of forward-looking language such as the words “goal,” “may,” “will,” “intend,” “expect,” “anticipate,” “estimate,” “project,” “would,” “could” or words with similar meaning or the negatives of these terms or by the discussion of strategy or intentions. The forward-looking statements in this release include express or implied statements regarding the use and adoption of QuantaFlo® by existing and new customers, and seeking a new 510(k) clearance for QuantaFlo® with expanded indications for use, among others. Such forward-looking statements are subject to a number of risks and uncertainties that could cause such forward-looking statements to differ materially from those discussed herein, such as risks associated with seeking a 510(k) clearance from the FDA, risks associated with previously marketing QuantaFlo® with provocative functional maneuvers in reliance on letters to file, as well as those risk factors affecting Semler’s business that are detailed in Semler’s filings with the Securities and Exchange Commission. These forward-looking statements involve assumptions, estimates, and uncertainties that reflect current internal projections, expectations or beliefs. There can be no assurance that such statements will prove to be accurate, and actual results and future events could differ materially from those anticipated in such statements. All forward-looking statements contained in this current report are qualified in their entirety by these cautionary statements and the risk factors described above. Furthermore, all such statements are made as of the date of this report and Semler assumes no obligation to update or revise these statements unless otherwise required by law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SEMLER SCIENTIFIC, INC.

Date: January 22, 2024

By: /s/ Douglas Murphy-Chutorian

Name: Douglas Murphy-Chutorian, M.D

Title: Chief Executive Officer
