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 4, 2021

SILK ROAD MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38847**	**20-8777622**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

1213 Innsbruck Drive
Sunnyvale, California 94089
(Address of principal executive office) (Zip Code)

(408) 720-9002

(Registrant's telephone number, including area code)

N/A

(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))

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $0.001 Per Share	SILK	The NASDAQ Global Select Market

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.

Silk Road Medical (the "Company") is providing an update on its ongoing investigation related to its voluntary recall of certain of its ENROUTE® Transcarotid Stent Systems, manufactured by Cordis, a Cardinal Health company (the "Manufacturer").

As a result of its testing and review of data supplied by the Manufacturer, the Company believes it has isolated the root cause which is related to a single operator that, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. All 6French crossing profile units (9mm-10mm stent diameter sizes) associated with these lots have already been recalled. The Company has received one new complaint of a tip detachment related to its 5French crossing profiles systems (5mm-8mm stent diameter sizes). The Company has not received any reports of strokes, deaths or other long-term patient sequalae, but has decided to voluntarily recall all 5French lots manufactured under similar conditions. The 5French recall comprises approximately 1,670 units in 47 lots.

The expanded recall impacts a total of 100 lots comprising approximately 3,770, units across both the 6French and 5French stent systems. The Company believes that the expanded scope of the recall covers all lots related to the issue under investigation and does not expect further voluntary actions to be taken.

Similar to the process undertaken with the 6French stent systems, the Company is working to replace customer inventory of the 5French stent systems with units outside of the recalled lots and believes that the Manufacturer is continuing to take steps to ensure product meets specification with minimal to no disruption in supply.

The Company has initiated a Supplier Correction Action Request (SCAR) per its Quality System. The Company plans to address the recall further during its fourth quarter earnings conference call.

This information is intended to be furnished under Item 7.01 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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.

Forward Looking Statements.

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements include statements made about the recall and Silk Road Medical's ongoing investigation. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include risks described in the section entitled Risk Factors and elsewhere in our filing made with the Securities and Exchange Commission in Silk Road's Quarterly Report on Form 10-Q filing made with the Securities and Exchange Commission on November 16, 2020. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Silk Road Medical disclaims any obligation to update these forward-looking statements. All forward-looking statements in this document are qualified in their entirety by this cautionary statement.

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, thereunto duly authorized.

SILK ROAD MEDICAL, INC.

Date: February 4, 2021

By: /s/ Erica J. Rogers
Erica J. Rogers
Chief Executive Officer