
**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 1, 2021

SILK ROAD MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38847
(Commission
File Number)

20-8777622
(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 2.02. Results of Operations and Financial Condition.

On March 1, 2021, Silk Road Medical, Inc. issued a press release regarding its financial results for the quarter and full year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information is intended to be furnished under Item 2.02 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Silk Road Medical, Inc. issued on March 1, 2021.

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: March 1, 2021

By: /s/ Erica J. Rogers
Erica J. Rogers
President, Chief Executive Officer and Director

Silk Road Medical Reports Fourth Quarter and Full Year 2020 Financial Results

Submitted PMA Supplement for ENROUTE Stent in Standard Surgical Risk Patients

SUNNYVALE, Calif. – March 1, 2021 – Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today reported financial results for the three months and full year ended December 31, 2020.

Silk Road Medical also announced it has submitted a Pre-Market Approval (PMA) supplement to the Food and Drug Administration (FDA) for the ENROUTE Transcarotid Stent System which is intended to expand indications for use to include the treatment of patients at standard risk for adverse events from carotid endarterectomy. This supplement follows the original PMA approval for the ENROUTE Transcarotid Stent System in high surgical risk patients.

“Throughout 2020, we made meaningful progress on our strategic, market development, and commercial goals which is a testament to the tenacity of our team and the underlying demand for TCAR,” said Erica Rogers, President and Chief Executive Officer of Silk Road Medical. “We are well positioned for growth and success in 2021 and beyond, as we work to drive deeper physician adoption and further expand our total addressable market.”

Fourth Quarter 2020 Financial Results

Revenue for the fourth quarter of 2020 was \$21.1 million, an increase of \$2.5 million or 13%, compared to the fourth quarter of 2019.

Gross profit for the fourth quarter of 2020 was \$15.9 million compared to \$13.9 million for the fourth quarter of 2019. Gross margin for the fourth quarter of 2020 was flat at 75% compared to the fourth quarter of 2019 as improvements in productivity were offset by the timing of previously announced investments in manufacturing engineering and infrastructure projects.

Operating expenses were \$30.9 million for the fourth quarter of 2020, compared to \$21.4 million in the corresponding prior year period, which represents an increase of 44%. The increase was driven by selling, general and administrative expenses related to growth in personnel and continued commercialization initiatives as well as the timing of certain research and development expenses, partially offset by the continued reduction in travel, tradeshow and other expenses due to COVID-19.

Net loss was \$16.8 million in the fourth quarter of 2020, or a loss of \$0.49 per share, as compared to a loss of \$8.3 million, or \$0.27 per share, in the corresponding period of the prior year.

Full Year 2020 Financial Results

Revenue for the full year 2020 was \$75.2 million, an increase of \$11.9 million or 19%, compared to 2019. The increase was driven primarily by growing adoption of TCAR across an expanded base of hospital accounts, trained physicians, and sales territories, partially offset by the impact of COVID-19.

Gross profit for the full year 2020 was \$53.9 million compared to \$47.4 million for 2019. Gross margin for the full year 2020 declined to 72% compared to 75% in 2019, driven by unfavorable production variances as a result of temporarily idled manufacturing operations due to COVID-19, and previously announced investments in manufacturing engineering and infrastructure projects. The decline was partially offset by the decrease in the provision for sales returns in the second quarter.

Operating expenses were \$96.8 million for the full year 2020, compared to \$75.5 million in the corresponding prior year period, which represents an increase of 28%. The increase was driven by the timing of certain research and development initiatives and selling, general and administrative expenses related to growth in personnel and

continued commercialization initiatives and partially offset by the continued reduction in travel, tradeshow and other expenses due to COVID-19.

Net loss was \$47.4 million in the full year 2020, or a loss of \$1.44 per share, as compared to a loss of \$52.4 million, or \$2.28 per share, in the corresponding period of the prior year. This metric for the full year 2019 included a \$21.0 million noncash charge resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability. We continued to record adjustments to the estimated fair value of the convertible preferred stock warrants until they were exercised in connection with our IPO offering in April 2019.

Cash, cash equivalents, and short-term investments were \$147.5 million as of December 31, 2020.

2021 Financial Guidance

Silk Road Medical projects revenue for the full year 2021 to range from \$102 million to \$108 million.

Conference Call

Silk Road Medical will host a conference call at 1:30 p.m. PT / 4:30 p.m. ET on Monday, March 1, 2021 to discuss its fourth quarter and full year 2020 financial results. The call may be accessed through an operator by calling (844) 883-3861 for domestic callers and (574) 990-9820 for international callers using conference ID: 3554549. A live and archived webcast of the event will be available at

<https://investors.silkroadmed.com/>.

About Silk Road Medical

Silk Road Medical, Inc. (NASDAQ: SILK), is a medical device company located in Sunnyvale, California, that is focused on reducing the risk of stroke and its devastating impact. The company's flagship procedure, TransCarotid Artery Revascularization (TCAR), is clinically proven to treat blockages in the carotid artery at risk of causing a stroke. For more information on how Silk Road Medical is delivering brighter patient outcomes through brighter clinical thinking, [visit www.silkroadmed.com](http://www.silkroadmed.com) and connect on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Forward-Looking Statements

This press release 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 regarding the impact of COVID-19 on our business, financial guidance, progress made on achieving our corporate goals, and the overall strength of our business and culture. 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.

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SILK ROAD MEDICAL, INC.
Statements of Operations Data
(Unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue	\$ 21,133	\$ 18,634	\$ 75,227	\$ 63,354
Cost of goods sold	5,217	4,721	21,291	15,927
Gross profit	<u>15,916</u>	<u>13,913</u>	<u>53,936</u>	<u>47,427</u>
Operating expenses:				
Research and development	10,036	3,264	21,271	12,272
Selling, general and administrative	20,872	18,156	75,524	63,220
Total operating expenses	<u>30,908</u>	<u>21,420</u>	<u>96,795</u>	<u>75,492</u>
Loss from operations	(14,992)	(7,507)	(42,859)	(28,065)
Interest income	152	441	1,104	1,656
Interest expense	(791)	(1,217)	(4,411)	(4,952)
Loss on debt extinguishment	(1,119)	—	(1,119)	—
Remeasurement of warrant liability and other income (expense), net	(6)	(8)	(80)	(21,054)
Net loss	<u>(16,756)</u>	<u>(8,291)</u>	<u>(47,365)</u>	<u>(52,415)</u>
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	(113)	—	37	2
Net change in other comprehensive loss	<u>(113)</u>	<u>—</u>	<u>37</u>	<u>2</u>
Net loss and comprehensive loss	<u>\$ (16,869)</u>	<u>\$ (8,291)</u>	<u>\$ (47,328)</u>	<u>\$ (52,413)</u>
Net loss per share, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.27)</u>	<u>\$ (1.44)</u>	<u>\$ (2.28)</u>
Weighted average common shares used to compute net loss per share, basic and diluted	<u>34,063,121</u>	<u>30,989,705</u>	<u>32,965,539</u>	<u>22,956,679</u>

SILK ROAD MEDICAL, INC.
Balance Sheets Data
(Unaudited, in thousands)

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 69,466	\$ 39,181
Short-term investments	78,016	51,508
Accounts receivable, net	9,070	8,601
Inventories	9,989	10,322
Prepaid expenses and other current assets	6,787	2,878
Total current assets	173,328	112,490
Long-term investments	—	18,224
Property and equipment, net	2,844	2,734
Restricted cash	310	310
Other non-current assets	2,832	3,644
Total assets	\$ 179,314	\$ 137,402
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 2,598	\$ 1,898
Accrued liabilities	16,957	15,034
Total current liabilities	19,555	16,932
Long-term debt	48,533	44,879
Other liabilities	3,726	3,700
Total liabilities	71,814	65,511
Stockholders' equity		
Preferred stock, \$0.001 par value	—	—
Common stock, \$0.001 par value	34	31
Additional paid-in capital	346,318	263,384
Accumulated other comprehensive income	39	2
Accumulated deficit	(238,891)	(191,526)
Total stockholders' equity	107,500	71,891
Total liabilities and stockholders' equity	\$ 179,314	\$ 137,402