

**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 12, 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 7.01. Regulation FD Disclosure.

On January 12, 2021, we are posting an investor presentation to our website (www.silkroadmed.com). A copy of this investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

By filing this Current Report on Form 8-K and furnishing the information contained herein, we make no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information contained herein, including the exhibit furnished hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation of Silk Road Medical, Inc. dated January 12, 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: January 12, 2021

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



JANUARY 2021

Forward Looking Statement

Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and Silk Road's own internal estimates and research. While Silk Road believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources and undertakes no obligation to update such information after the date of this presentation. While Silk Road believes its internal research is reliable, such research has not been verified by any independent source.

This presentation contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, our future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, current and prospective markets or products, clinical activities, regulatory approvals, drug market acceptance, and plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this presentation represent our views as of the date of this presentation. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Such statements are based on 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 in our most recent 10-K filing and 10-Q filings made with the Securities and Exchange Commission. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

By attending or receiving this presentation you acknowledge that you will be solely responsible for your own assessment of the market and our market position and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of our business.



Ushering in a **new era**
of minimally-invasive
transcarotid therapies



\$5.1B Global TCAR Opportunity

Market Strategy

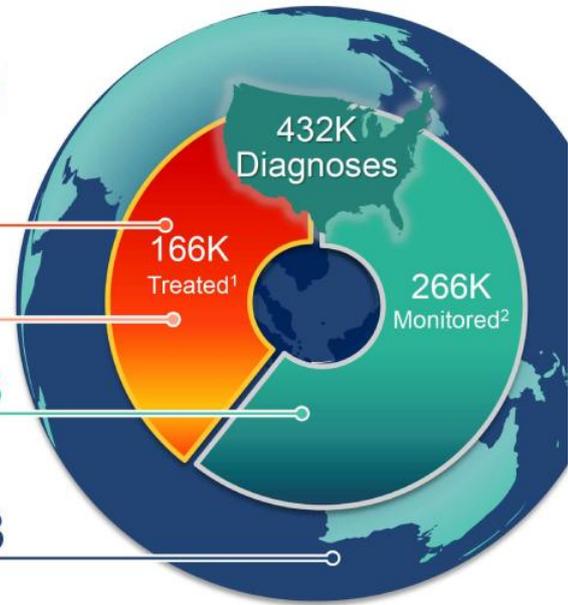
1 **Convert** current procedures **\$1.1B**
Established market with suboptimal treatments

✓ **\$707M High Surgical Risk, ~2/3 or 110K procedures**

○ **\$360M Standard Surgical Risk, ~1/3 or 56k procedures**

2 Treat today's **untreated** **\$1.7B**
TCAR changes risk / reward

3 Expand **internationally** **\$2.3B**



Sources: Modus Health Group data for 2019; GlobalData Carotid and Renal Artery Stents Global Market Model, 2015-2030; Internal estimates. Note: US opportunity calculated as procedure volume multiplied by average sales price of each TCAR product (1 unit each) (1 unit each)

¹ Treated with CEA, CAS, or TCAR; does not include patients who undergo medical management alone; Includes both standard and high surgical risk

² Includes patients who did not undergo a surgical or endovascular procedure in 2019 and were instead monitored and treated with medical management alone



Carotid Artery Disease – 33% of Ischemic Strokes

Cause of stroke



Plaque fragments
break off and move to brain



Prevalence

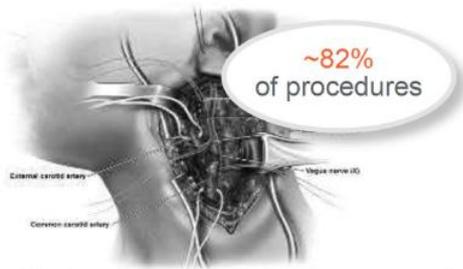
4.3M people in US have carotid stenosis

Source: Weerd M Stroke 2010; Modus Health Group for 2019,
Vascularweb.org
5

SILI

New Era of Minimally-Invasive Transcarotid Therapies

SURGICAL:
Carotid Endarterectomy (CEA)
65 years



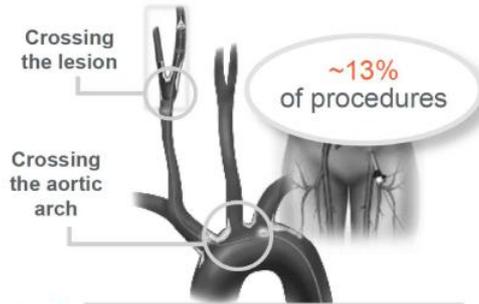
HIGHER RATE
of procedural complications



LOW 30-day stroke risk

A Dated Standard of Care

ENDOVASCULAR:
Transfemoral Carotid Artery Stenting (CAS)
Since the '90s



LOWER adverse events



HIGHER (~2x)
30-day stroke risk

A Niche Procedure

**TransCarotid Artery
Revascularization (TCAR)
A New Era**



LOWER adverse events



LOW 30-day stroke risk

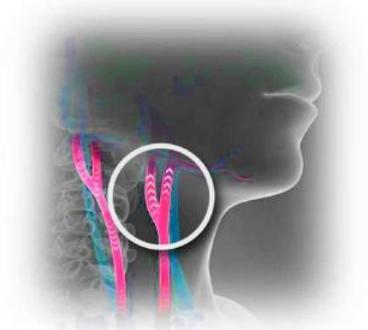
Paradigm Shift in Carotid Revascularization



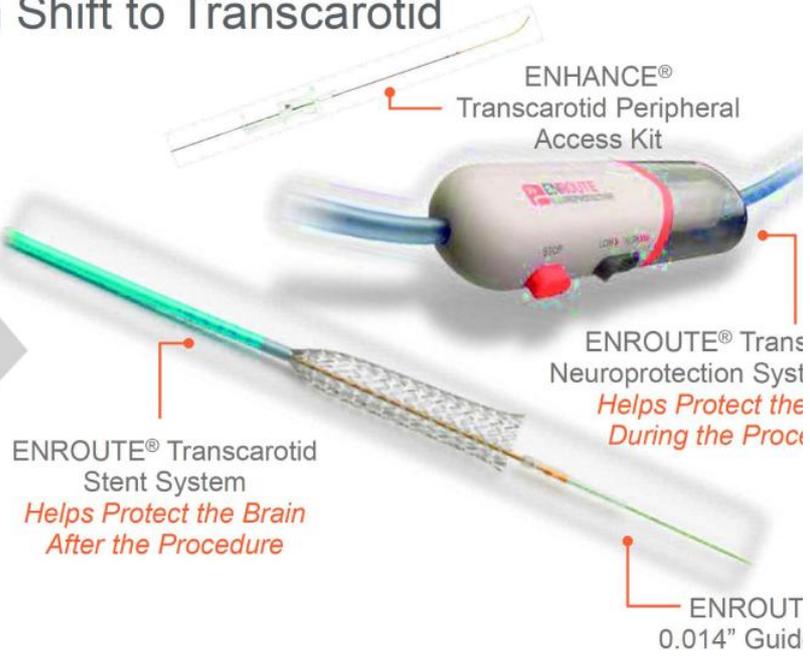
TCAR Portfolio

Paradigm Shift to Transcarotid

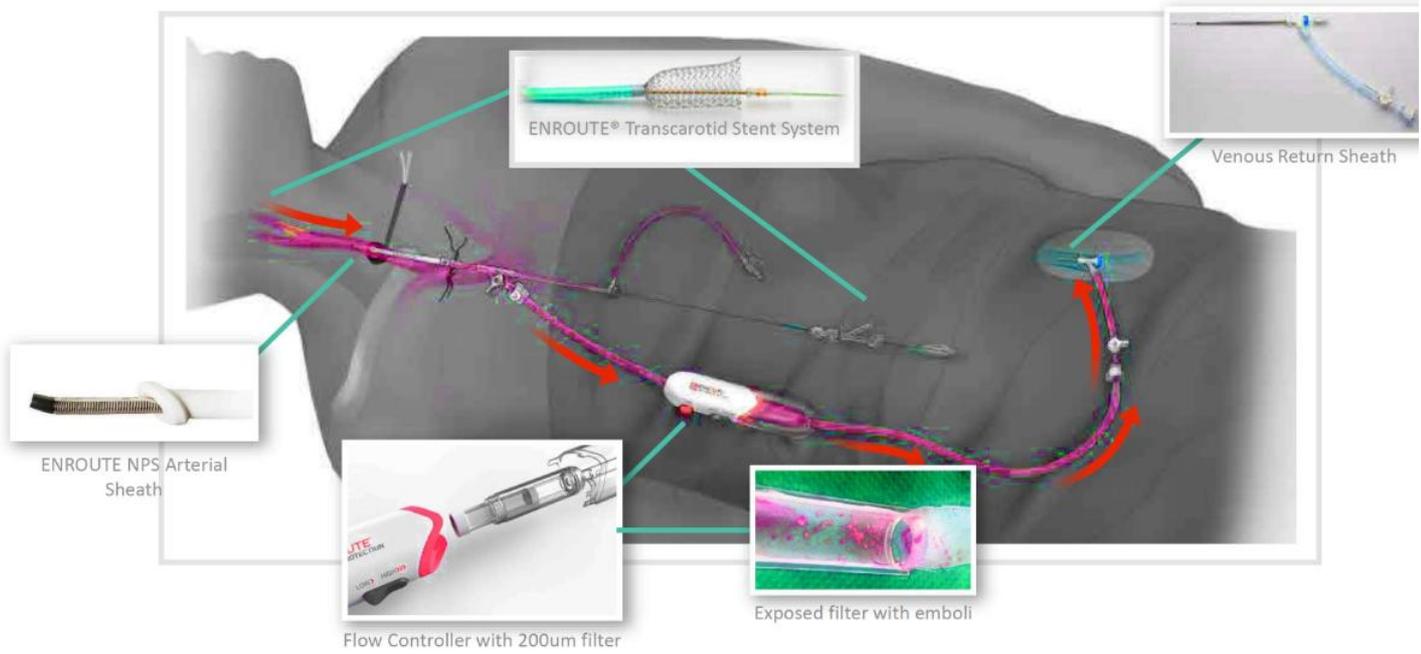
Direct Carotid Access



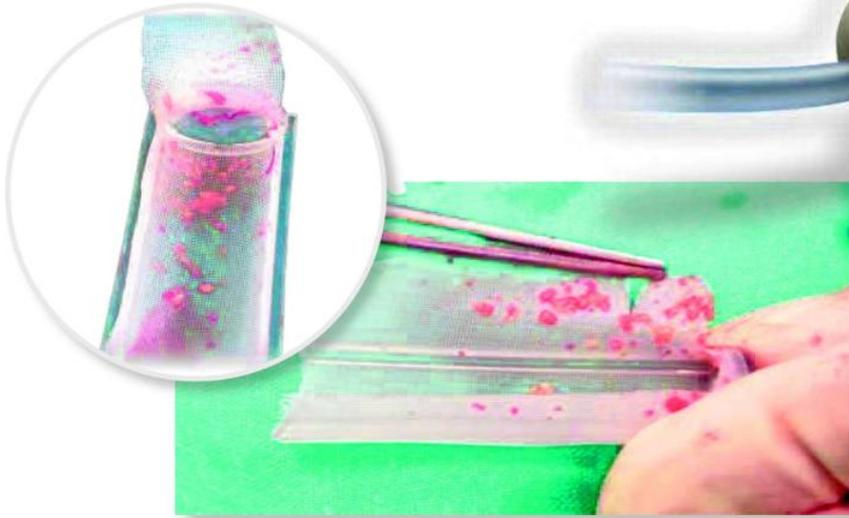
Robust Flow Reversal



ENROUTE® Stent & Transcarotid Neuroprotection System in Ac



The proof
is in the filter



25,000+
TCAR procedures
worldwide¹

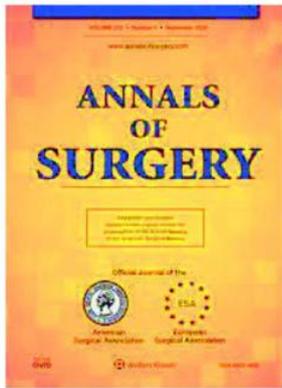
¹ Silk Road Medical Third Quarter 2020 Earnings Call on November 10, 2020

Momentum in U.S. Carotid Artery Disease Market



Relentless Focus on Patient Outcomes
Every patient.
Every day.

Ongoing Validation of TCAR



Compelling Outcomes^{1,2,3}

>7,000 patients worth of data published since 2019

- Low periprocedural stroke and death rates
- Lower odds cranial nerve injury
- Lower odds myocardial infarction
- Lower odds hospital stay >1 c

¹ Vikram S. Kashyap MD, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. *Stroke*. August 19, 2020; 51:2620–2629. DOI: 10.1161/STROKEAHA.120.030550

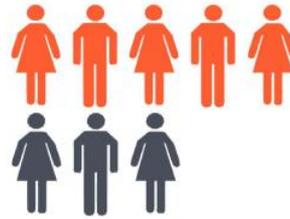
² Mahmoud B. Malas MD, MHS; Hanaa Dakour-Arudi MD; Vikram S. Kashyap MD, et al. TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. *Annals of Surgery*. September 15, 2020; 322(23):2313–2322. DOI: 10.1097/SLA.0000000000004496

³ Marc L. Schermerhorn, MD, Patric Liang, MD, Jens Eldrup-Jorgensen, MD, et al. Revascularization vs Transfemoral Carotid Artery Stenting with Stroke or Death among Patients with Carotid Artery Stenosis. *The Journal of the American Medical Association*. 2019; 322(23):2313–2322. DOI: 10.1001/jama.2019.18441

Efficiencies of a **Less Invasive Approach**

Average Procedure Time¹

TCAR **73 Mins** vs CEA **121 Mins**



Ability to treat **67% more** patients vs. CEA

Cost of Operating Room Time²

TCAR **\$2,701** vs CEA **\$4,447**



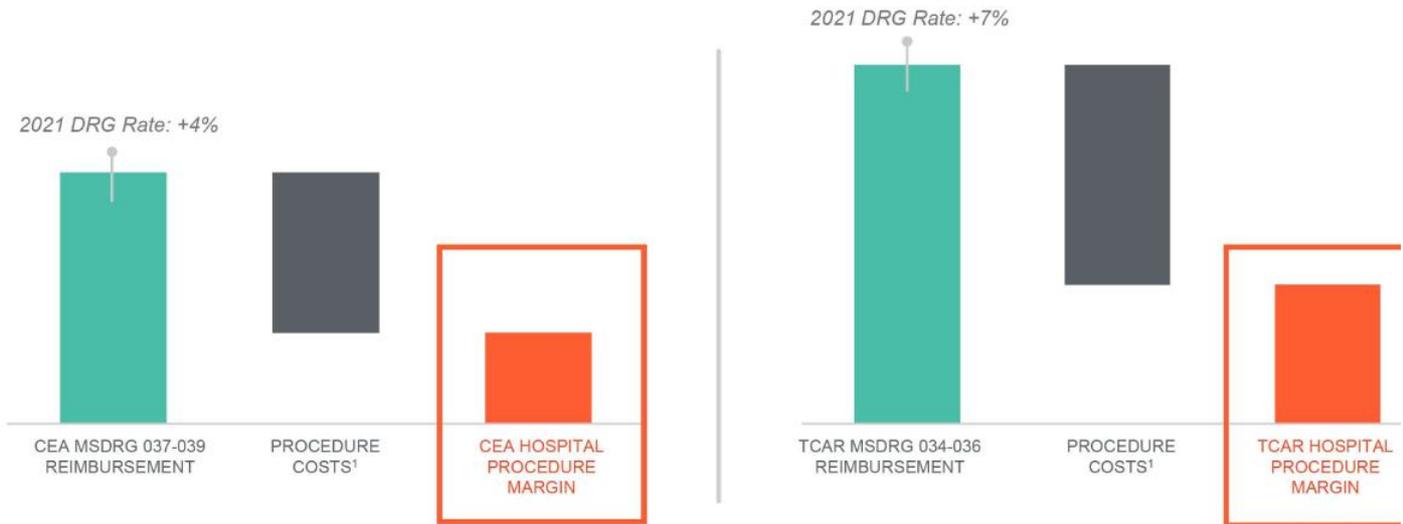
Reduced OR Time Cost over CEA: **\$1,776**

¹ Annals of Surgery 2020 - M. Malas, Transcarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project

² Childers et al. JAMA Surg 2018 Apr; 153(4)* with protamine use; Based on average procedure cost in national survey data

Procedure Margin

Economic Value Proposition Supporting Utilization



Hospital stay margin: TCAR furthers the economic advantage by reducing in-hospital complications and length of stay

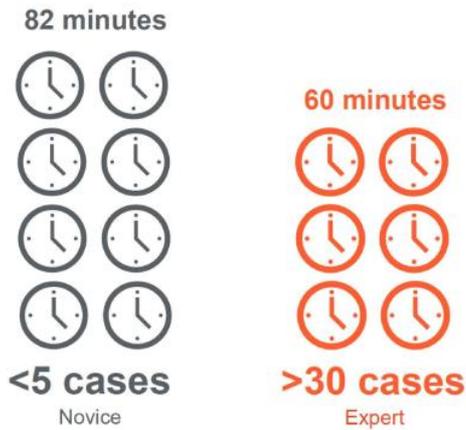
Source: Health Advances and company analysis

¹ Procedure costs include OR time, devices, medication, overhead, etc. Excludes hospital length of stay expenses.



Easy-to-Learn Procedure with Many Physicians Trained

Decreasing **operative time** with experience...



No significant differences¹ in major in-hospital outcomes were found regardless of experience level...

- ✓ Stroke
- ✓ Death
- ✓ Composite stroke/death/M

Source: Kashyap, V.S., A.H. King et al. "Learning Curve for Surgeons Adopting Transcarotid Artery Revascularization Based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project." *Journal of American College of Surgeons* (2019), doi: <https://doi.org/10.1016/j.jamcollsurg.2019.09.020>.

¹ Expert physicians were more likely to treat patients with moderate or severe congestive heart failure, novice and intermediate physicians were more likely to treat patients with prior CEA or CAS, and advanced and expert physicians were more likely to treat patients with CMS medical high-risk criteria.



Physician Training Pivot

National TEST Drive Program

Q2 2020

Virtual / Regional



- In-person didactic
- Large cohorts hands-on

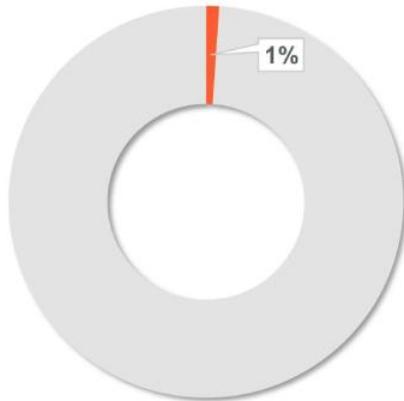
- Online didactic
- Smaller group, regional hands-on



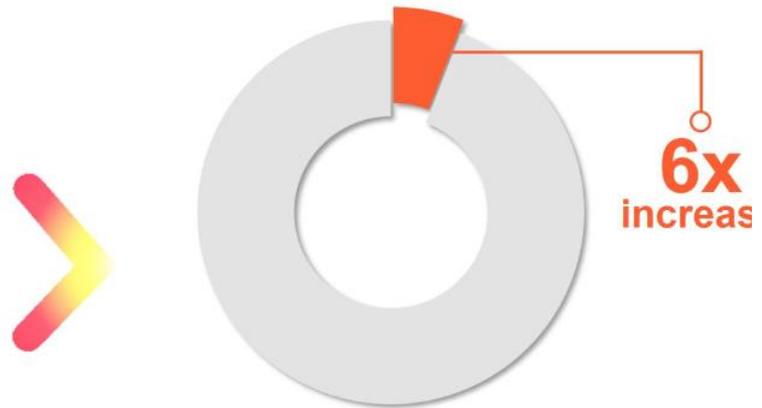
Commercial Strategy: Where Are We Now?

Establishing TCAR in Large, Unpenetrated Opportunity

US Market Share as of Q4 2017¹



US Market Share as of Q3 2020¹

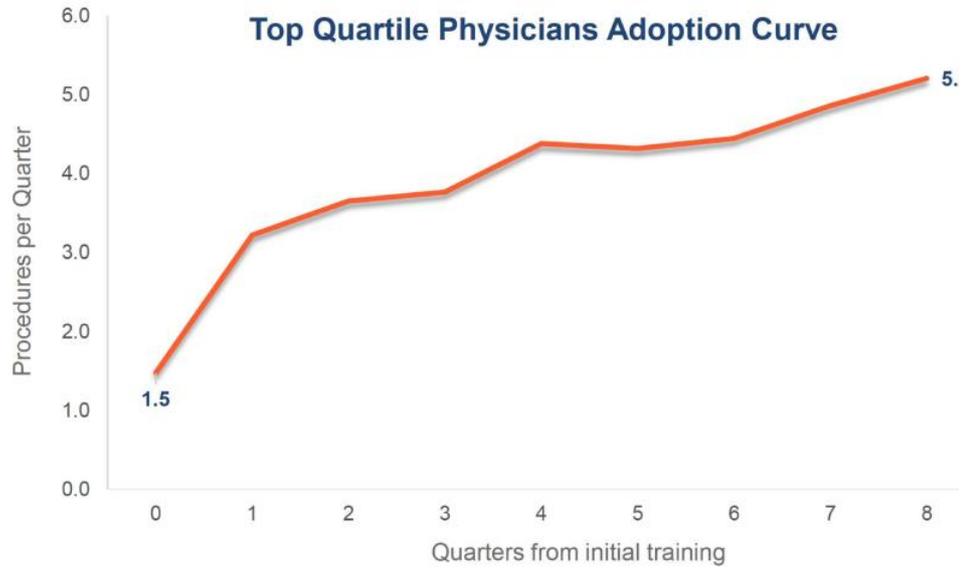


Commercial Strategy: Deepening US Adoption

Substantial Potential in Trained Physician Base

~1,770
Physicians trained
as of YE 2020¹

~55%
were trained within
last 8 quarters



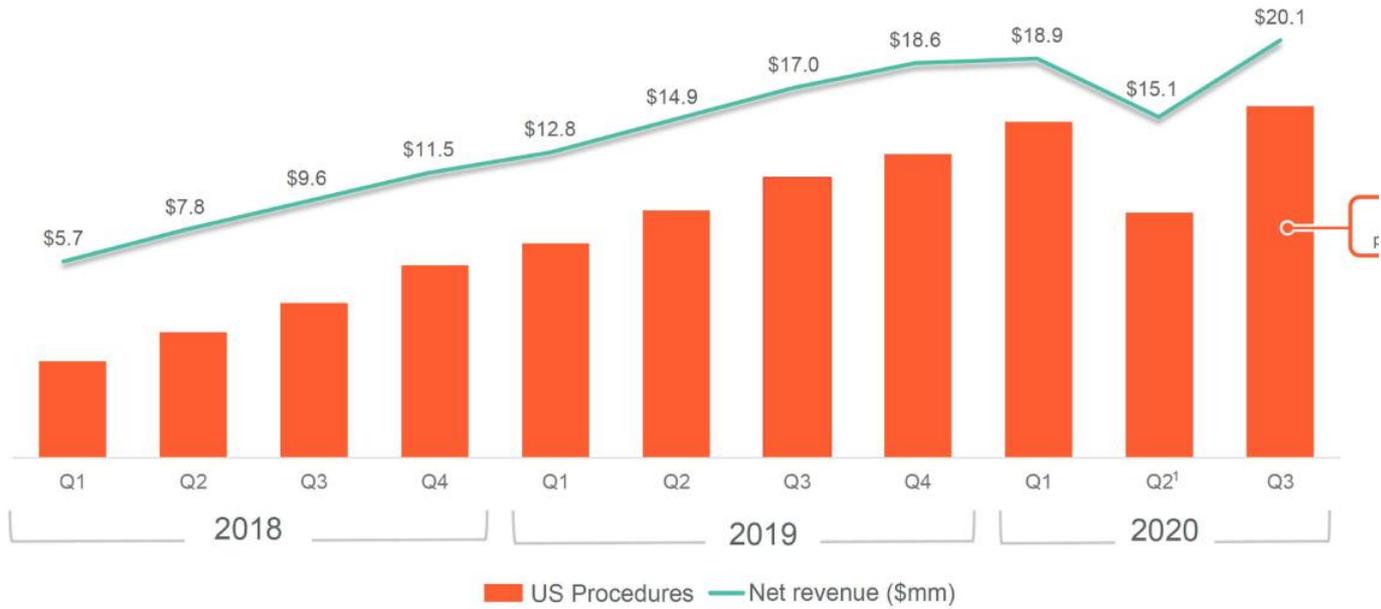
¹ 2020 guidance as of 3Q20 Earnings Call

² Average Procedures per Physician for first eight quarters from initial training for Top 25% of all TCAR-certified physicians trained > Q4 2016. Top 25% is calculated for each annual training cohort (pre-2017, 2017, 2018, 2019, 2020) and combined.



Growing TCAR Adoption

Utilization-Driven Revenue



¹ Second quarter revenue in 2020 included the recognition of \$1.3 million in deferred revenue due to a decrease in the provision for sales returns related to certain prior sales with a shorter shelf life, coupled with the downward trend in the company's historical returns rate



Meaningful Outcomes and Experiences

Physician Experience with TCAR during the Pandemic



Michael C. Stoner, M.D.
Chief of Vascular Surgery
University of Rochester Medical Center

“TCAR is **super predictable**. They’re out in 24 hours. You can keep marching these people through and prevent the disability they would have with a stroke.”

“This procedure can be done reliably on incredibly sick people in an almost collapsing healthcare system around

Ushering in a New Era of Transcarotid Therapies

Deepening U.S. TCAR Adoption

- Mounting Wave of Clinical Evidence
- Emphasis on Economic Value Proposition
- World-class Training and Commercialization Expertise



Expanding Beyond Core Market

- TCAR Product Expansion
- Leveraging Transcatheter Expertise to Neurovascular Market
- Expanding International Presence

SILKROAD 
MEDICAL®



