
**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): August 27, 2019

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))

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 August 27, 2019, 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>
<u>99.1</u>	<u>Investor Presentation of Silk Road Medical, Inc. dated August 27, 2019</u>

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: August 27, 2019

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

The logo for SilkRoad Medical is positioned in the upper right quadrant of the page. It features the word "SILKROAD" in a bold, white, sans-serif font, with a white chevron symbol pointing to the right at the end of the word. Below "SILKROAD" is the word "MEDICAL" in a smaller, dark grey, sans-serif font, followed by a registered trademark symbol (®). The background of the top half of the page is a solid orange color with a large, semi-transparent white chevron shape pointing to the right, which serves as a backdrop for the logo.

SILKROAD 
MEDICAL[®]

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. 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, degree of 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 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 most recent 10-Q filing 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.



Commercial-stage company that has established an **entirely new**, minimally invasive **procedure** with potential to become the **standard of care** in a multi-billion \$ market



TCAR

for
Stroke
Prevention

~2,000
Q2 US Procedures
(<5% market penetration¹)

>10,000
WW Procedures

\$60-62M
2019 Exp. Revenue
(74-79% YoY growth)

Figures as of 2Q 2019
¹ Represents Q1 annualized figure relative to total carotid procedures in 2018 of 168,000

Relentless Focus on Patient Outcomes
Every patient.
Every day.

Carotid Artery Disease –

33% of Ischemic Strokes

Cause of stroke



Plaque fragments
break off and move to brain



Current Prevalence

4.3M people in US have carotid stenosis

Source: Weerd M Stroke 2010; Modus Health Group 2018, Vascularweb.org

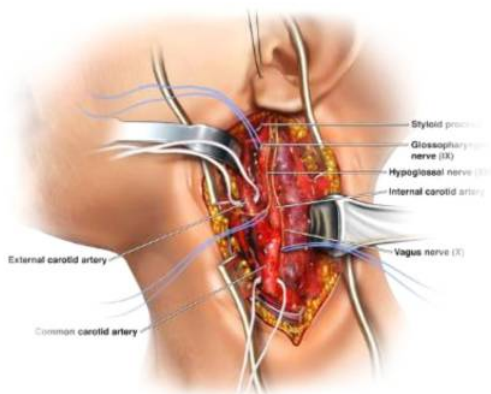
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A Dated Standard of Care

Carotid Endarterectomy

65 years



Major Adverse Event
Collateral Damage

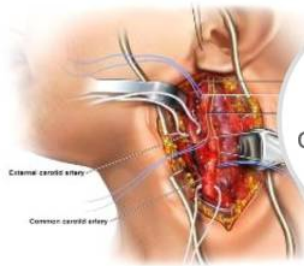
↓ Hospital Economic

↓ Accountable Care

“CAS: An Unacceptable Tradeoff”

SURGICAL:

Carotid Endarterectomy
(CEA)
65 years



~83%
of procedures



SIGNIFICANT adverse events

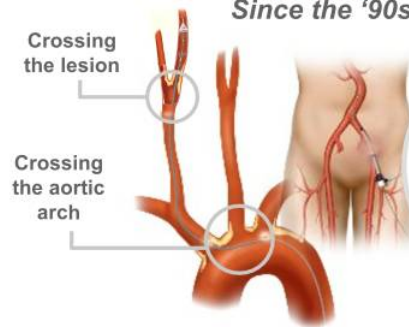


LOW 30-day stroke risk

A Dated Standard of Care

ENDOVASCULAR:

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



~14%
of procedures¹



LOWER adverse events



HIGHER (~2x) 30-day stroke risk

A Niche Procedure

Source: Modus Health Group 2018
¹ Excludes 2018 TCAR procedures

A ~\$2.6B Annual US Treatment Opportunity in 2018

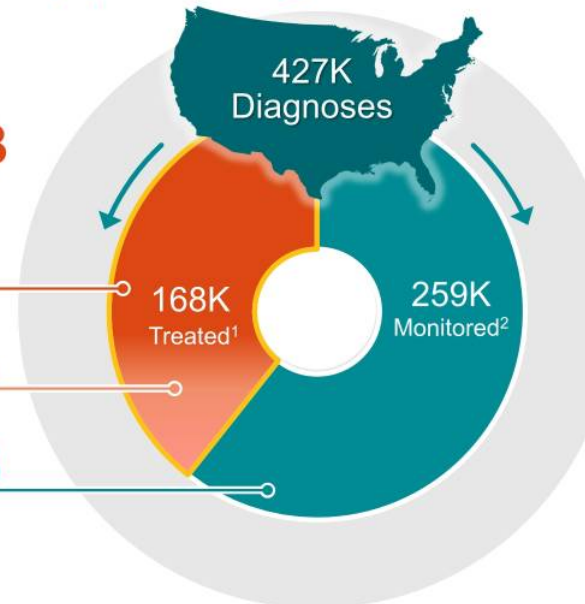
Greenfield opportunity

1 **Convert** current procedures
Established market with suboptimal treatments **\$1.0B**

✓ **\$665M High Surgical Risk, ~2/3 or 111K procedures**

○ **\$340M Standard Surgical Risk, ~1/3 or 57k procedures**

2 Treat today's **untreated**
TCAR changes risk / reward **\$1.6B**



A New, Minimally Invasive Procedure with Clinical Advantages

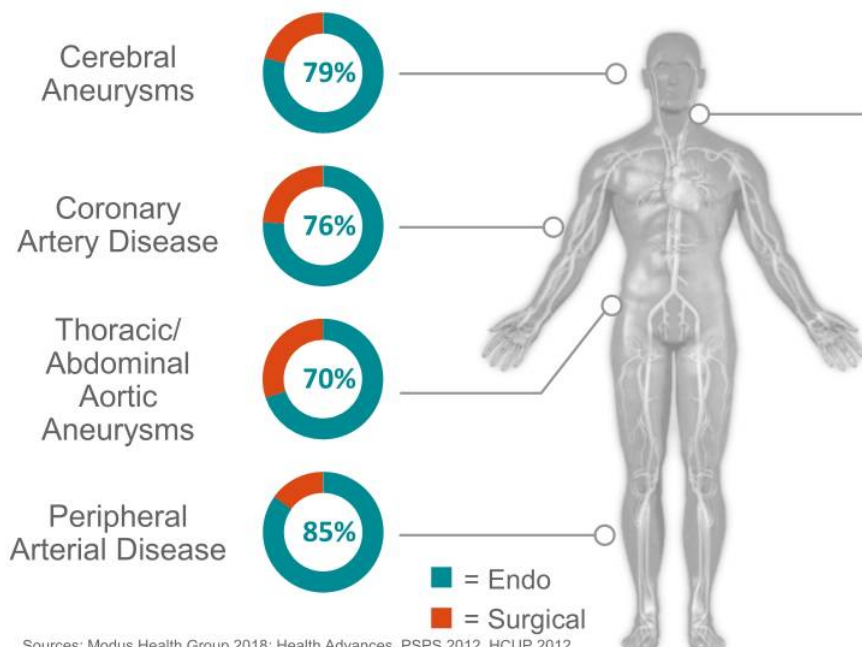
Source: Modus Health Group data for 2017 and 2018; note: US opportunity calculated as procedure volume multiplied by average sales price of each TCAR product (1 unit each)

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 2018 and were instead monitored and treated with medical management alone

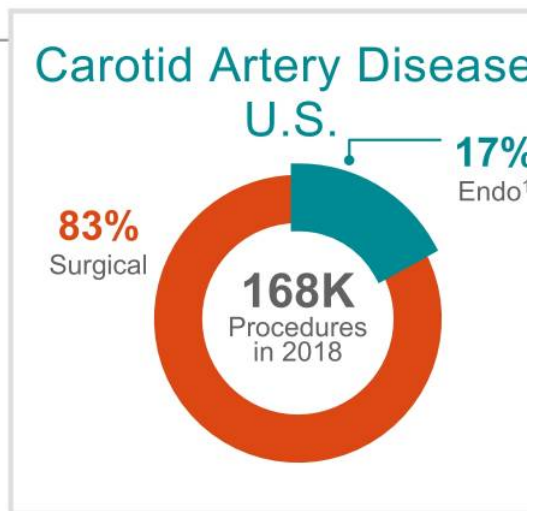
The New Normal:

Endovascular Procedures



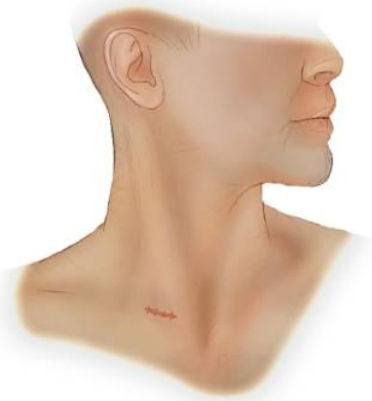
Sources: Modus Health Group 2018; Health Advances, PSPS 2012, HCUP 2012
¹ Includes ~3% represented by TCAR procedures in 2018

THE LAST FRONTIER: Open to Endo Conversion



TCAR is the Solution

TCAR Paradigm Shift: Transcarotid



Minimally Invasive



Avoids Aortic Arch



Avoids Cranial Nerve Plexus



High Rate Flow Reversal Neuroprotection

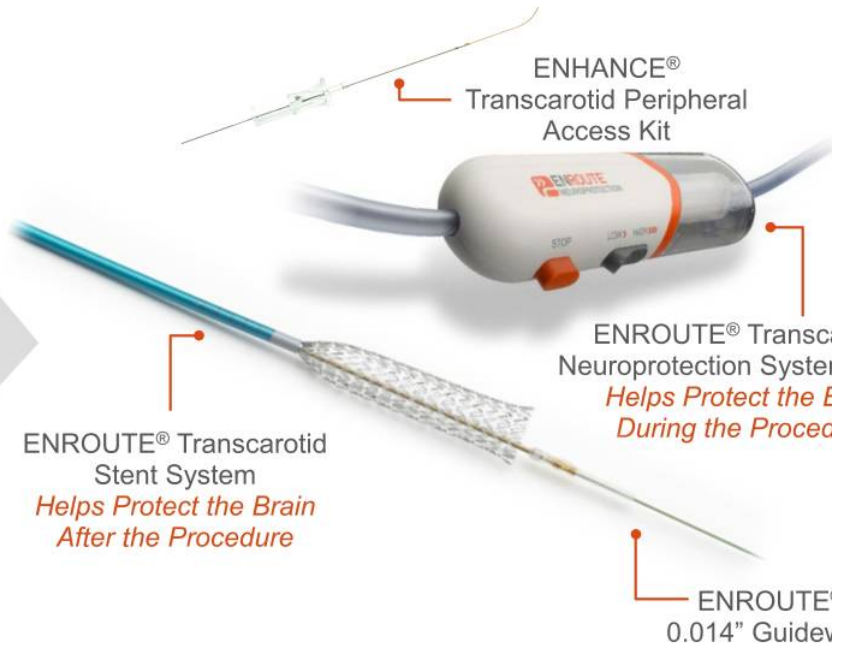
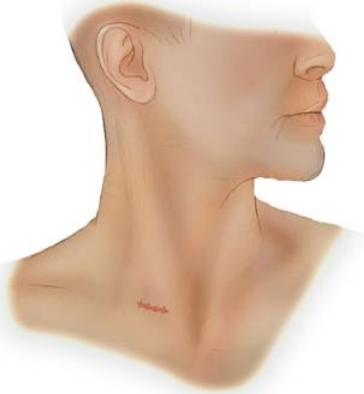


Accurate stenting

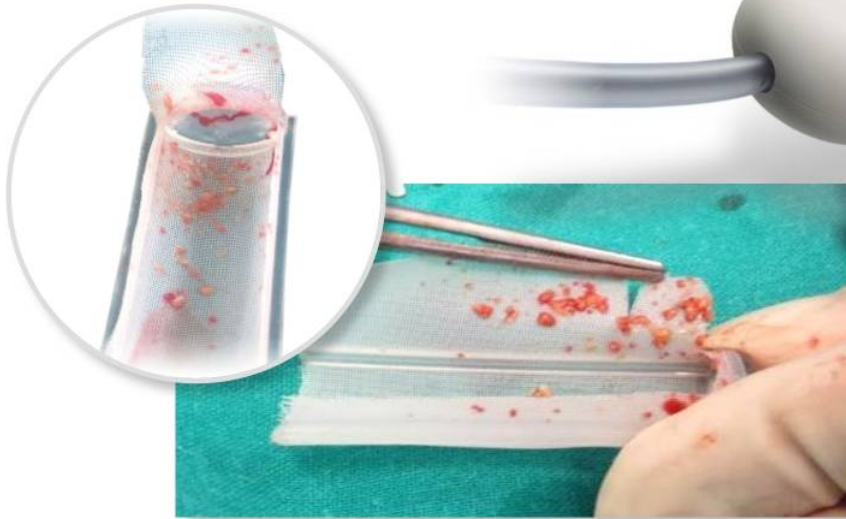
TCAR combines advantages from both worlds: **surgical principles** of neuroprotection and game changing **endovascular technology**

TCAR

Carotid-Specific Design, Dedicated Portfolio



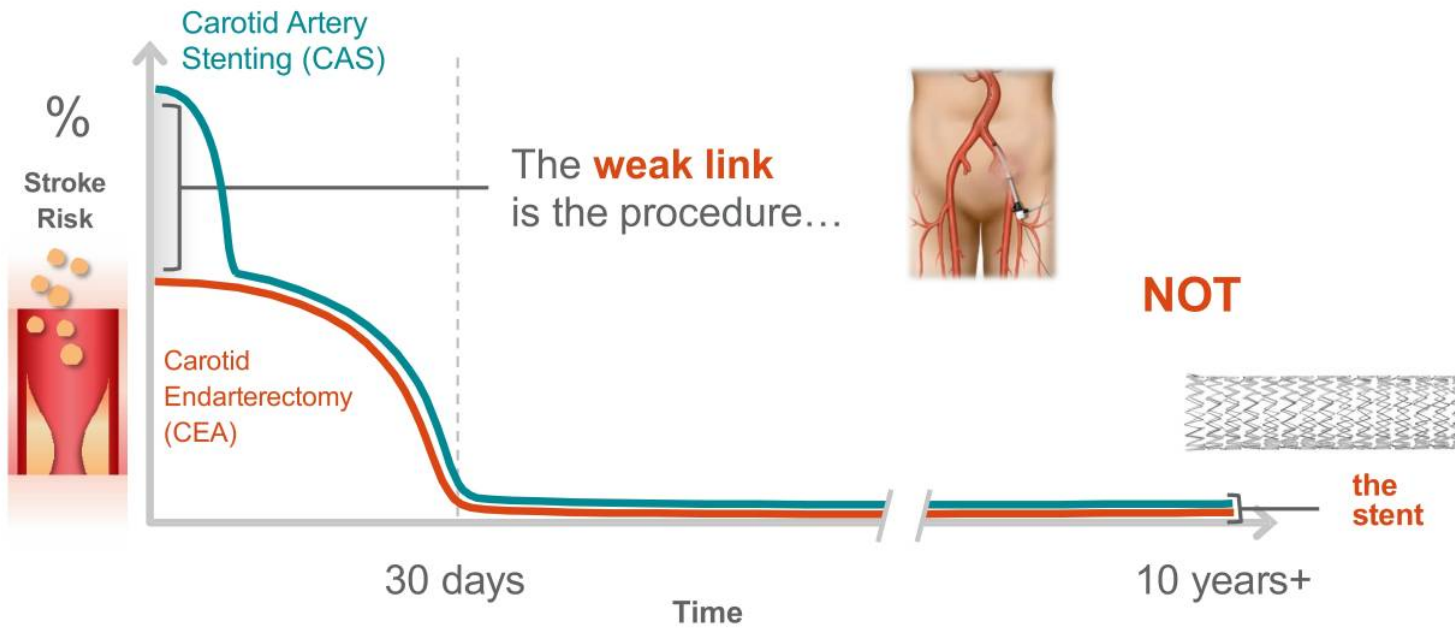
The proof
is in the filter



>10,000
TCAR procedures
worldwide¹

¹ As of 04/30/2019

Proven Stent Durability



Source: CREST 10-year follow-up, N Engl J Med 2016; 374:1021-1031.

Clinical Trials: 30 Day Stroke

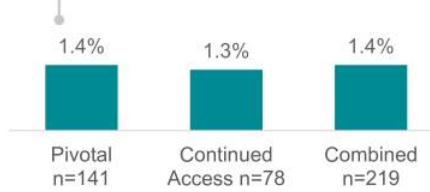
ROADSTER Trial Design and Purpose

- 1st time TCAR in the US
- 1st generation NPS
- Supported 510(k) clearance of NPS
- Supported PMA for ENROUTE Stent

ROADSTER¹

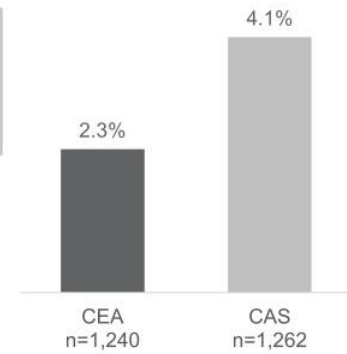
*"The overall **stroke rate of 1.4%** is the **lowest reported to date** for any prospective, multi-center trial of carotid stenting."*

– J Vasc Surg 2015;62:1227-35



High Surgical Risk

CREST²

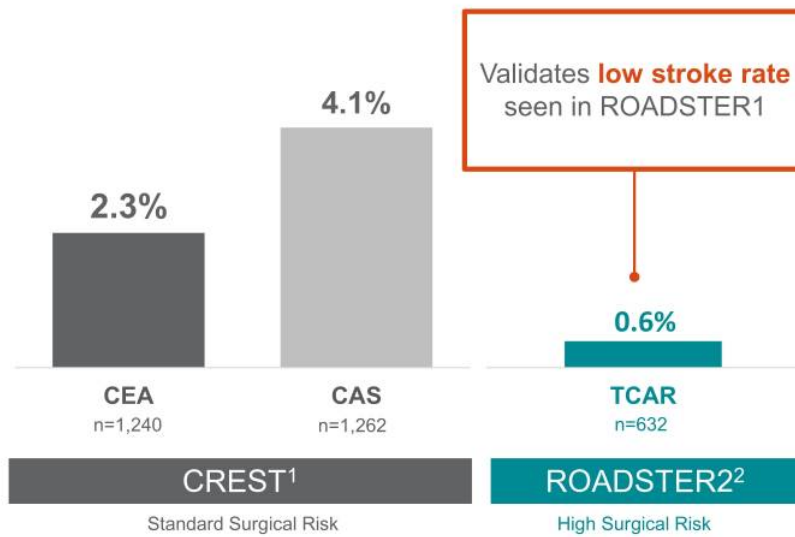


Standard Surgical Risk

¹ J Vasc Surg 2015;62:1227-35; ROADSTER outcomes presented on an "intention to treat" basis
² N Engl J Med 2010; 363:11-23

Growing Clinical Evidence

ROADSTER2 Real World Registry: 30 Day Stroke



Confirms Short Learning Curve

80% of enrolled physicians new to TCAR

Low Rates of 30-Day MAEs

Stroke/Death/MI (1.7%), Stroke/Death (0.8%), acute CNI (1.3%) and permanent CNI (0.5%)

Low 30-Day Stroke Rate in Vulnerable Sub-Groups

Symptomatic (0.6%), Female (0.5%) and Age >=75 (1.1%)

¹ N Engl J Med 2010; 363:11-23

² Kashyap, Vikram. "Analysis of the Early Outcomes in the ROADSTER-2 Clinical Trial of Transcarotid Artery Revascularization in Patients with Significant Carotid Artery Disease". Presentation, Society for Vascular Surgery 2019 Vascular Annual Meeting, National Harbor, MD, June 15, 2019.
Note: ROADSTER2 data per FDA Analysis (Per Protocol)

14 Note: Major adverse events (MAEs); myocardial infarction (MI); cranial nerve injury (CNI)

SILKROAD
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Unprecedented alignment

TCAR



September 2016

SVS | VQI
VASCULAR QUALITY INITIATIVE

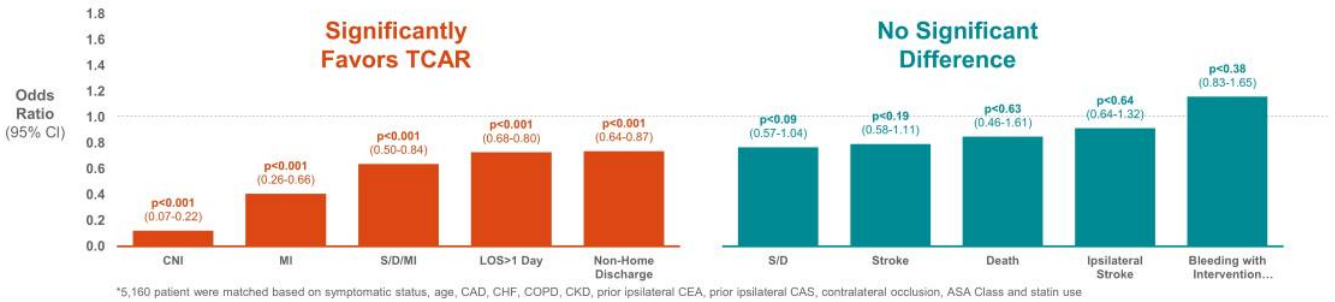


High Surgical Risk: Symptomatic and Asymptomatic

Challenging the Standard of Care

Matched Population: 5,160 TCAR Patients vs. 5,160 CEA Patients

TCAR Surveillance Project



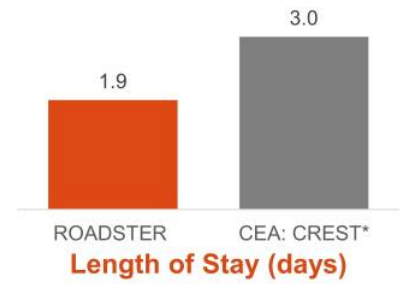
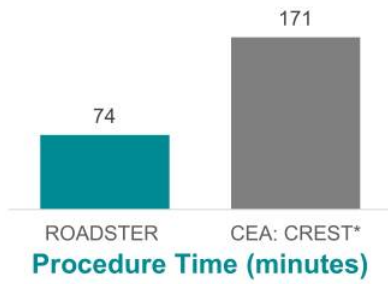
When receiving TCAR vs CEA, a patient is ...	Percentage	Description
less likely to have CNI	87%	
less likely to have MI	59%	
less likely to have S/D/MI	35%	
less likely to have an extended stay past one day	25%	
less likely to be discharged to a non-home facility (e.g. skilled nursing facility)	25%	

¹ Outcomes data represent propensity score, in-hospital outcomes
 Malas, Mahmoud. "Outcomes of TransCarotid Artery Revascularization (TCAR) versus Carotid Endarterectomy (CEA) in the TCAR Surveillance Project." Presentation, Society for Vascular Surgery 2019 Vascular Annual Meeting, National Harbor, MD, June 13, 2019.

TCAR: Established Codes and Payment

Physician: CPT Code		
TCAR	37215	\$1,050
CEA	35301	\$1,187

Hospital: ICD-10 Codes		
TCAR	DRGs 034-36	\$13,850
CEA	DRGs 037-39	\$9,360



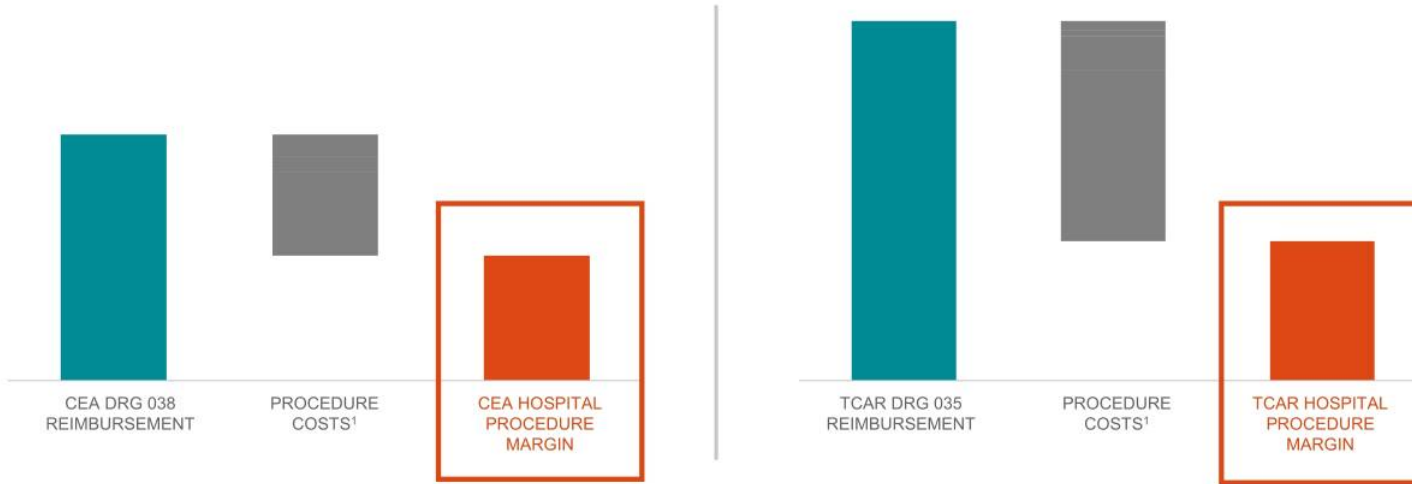
Medicare national average payment levels for CPT in 2019 and DRG figures in 2020
 *Standard Surgical Risk patients (ROADSTER High Surgical Risk)

17 / CONFIDENTIAL AND PROPRIETARY

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Procedure Margin

Economic value proposition easily understood by Value Analysis Committees



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.

18 / CONFIDENTIAL AND PROPRIETARY

Why Vascular Surgeons **Have Adopted** TCAR

which is moving towards the standard of care

Growing clinical
evidence base



P2P influence & inter/i
specialty competition

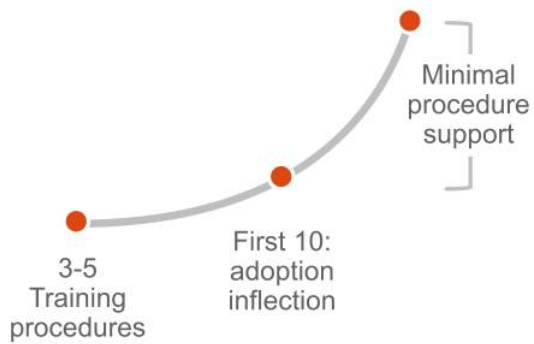
Quality initiatives and
economic incentives

Better patient and
physician experience

Easy-to-Learn Procedure

with Many Physicians Trained

Indicative Short Learning Curve



Commercial Strategy: Efficient Go-to-Market

Concentrated Market

~2,750 physicians perform
~80% of procedures¹



PHYSICIANS TRAINED

Clinically-Focused Direct Sales Force

Concentrated
hospital base and
procedure volume
drives **efficient**
coverage model

Growing Adoption



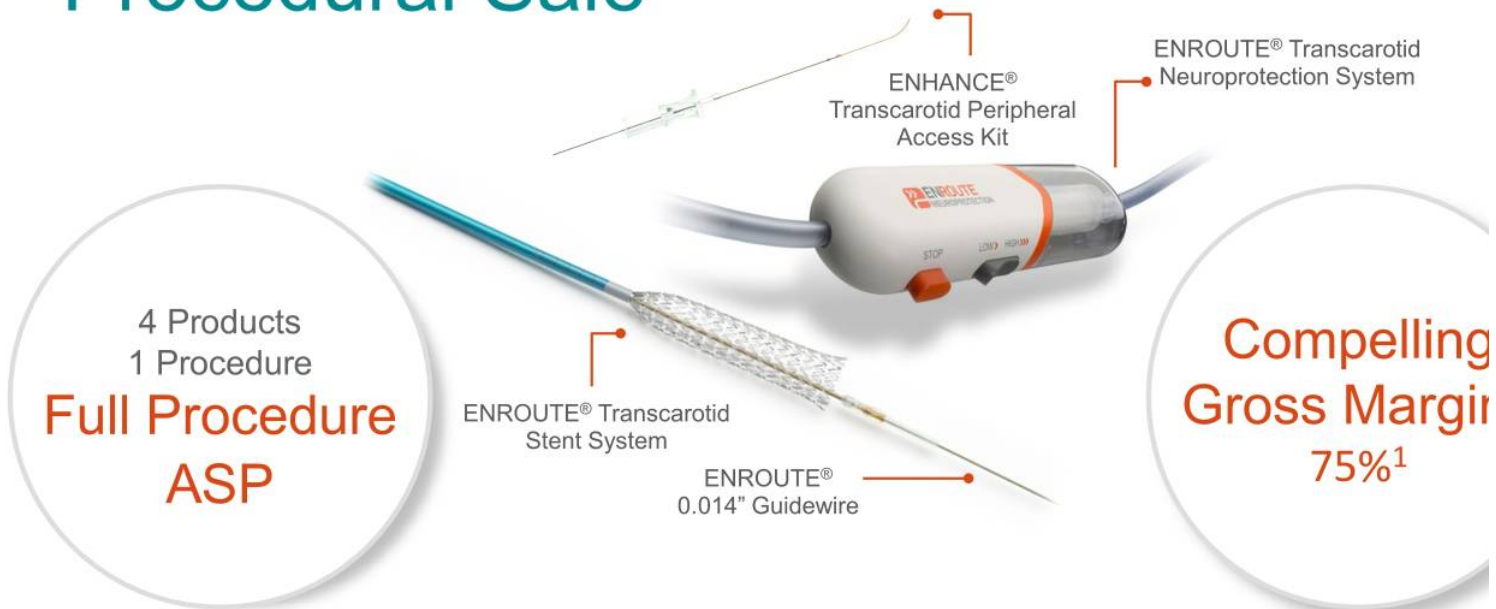
U.S. PROCEDURES

¹ Data as of 12/31/18 (Source: Independent 3rd Party Market Data)

² Outlook as of 07/29/2019

Attractive Business Model

Procedural Sale

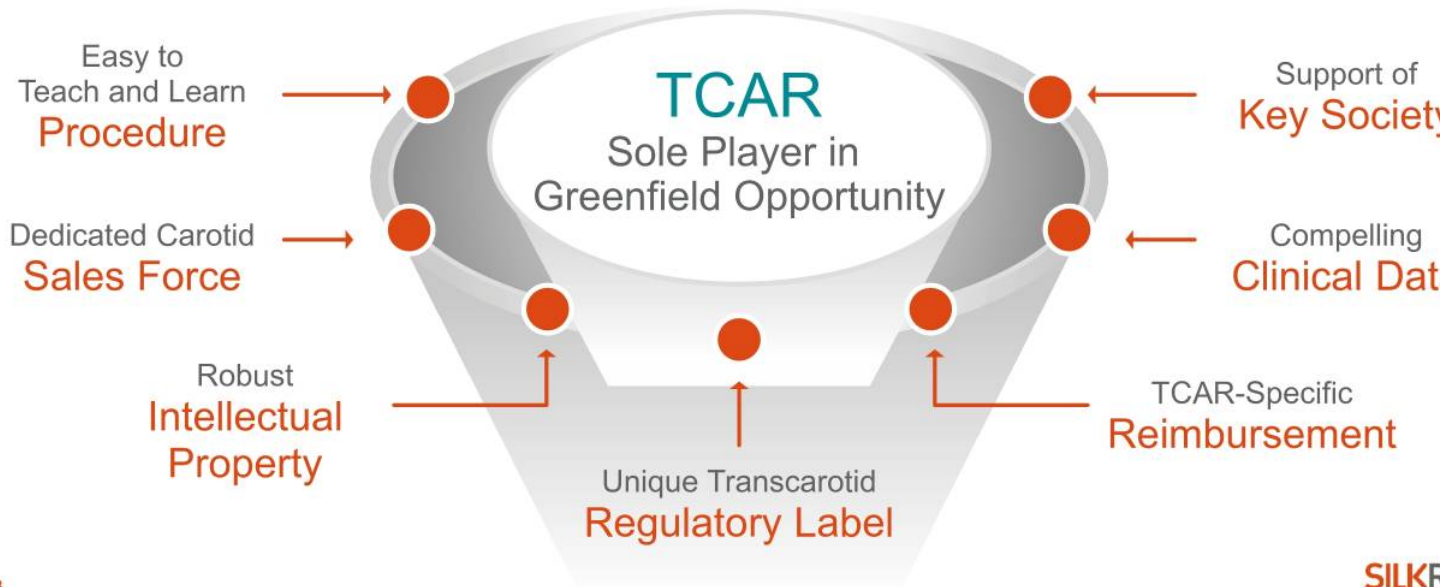


4 Products
1 Procedure
**Full Procedure
ASP**

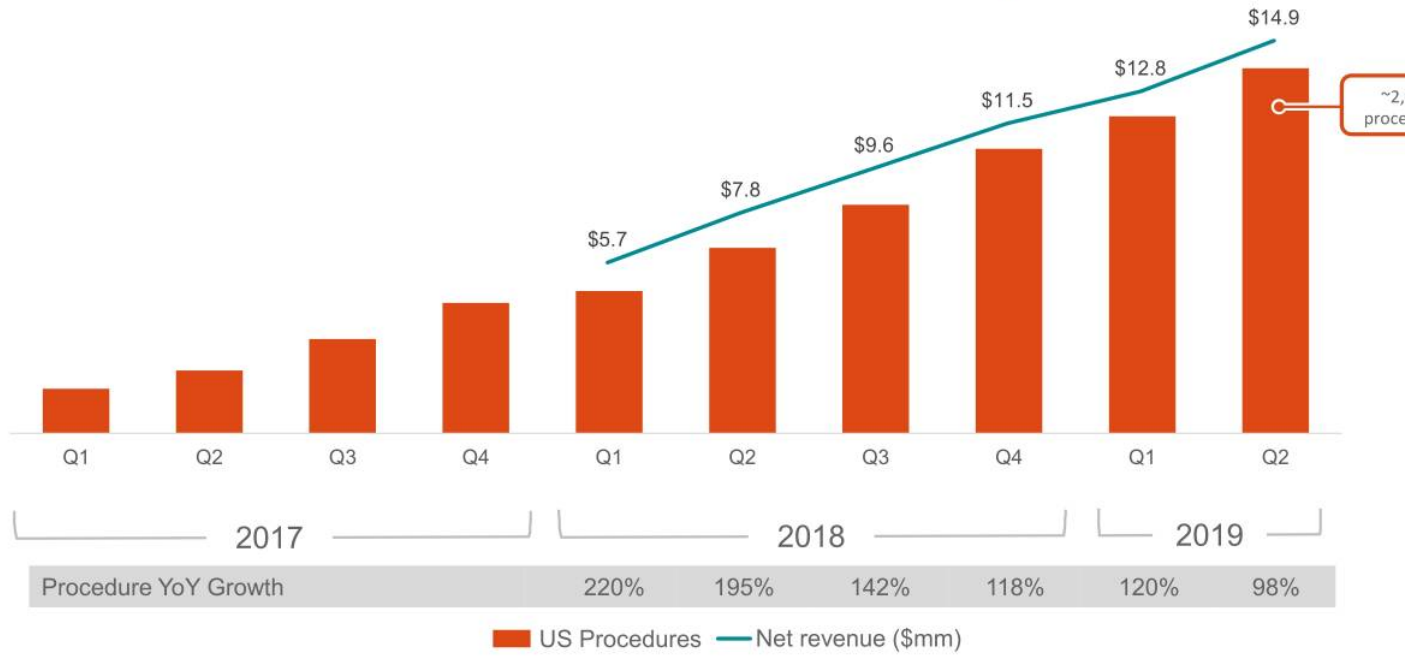
**Compelling
Gross Margin
75%¹**

¹ Six months ended June 30, 2019

Building and Maintaining a Sustainable Competitive Advantage



Procedure-Driven Ramp

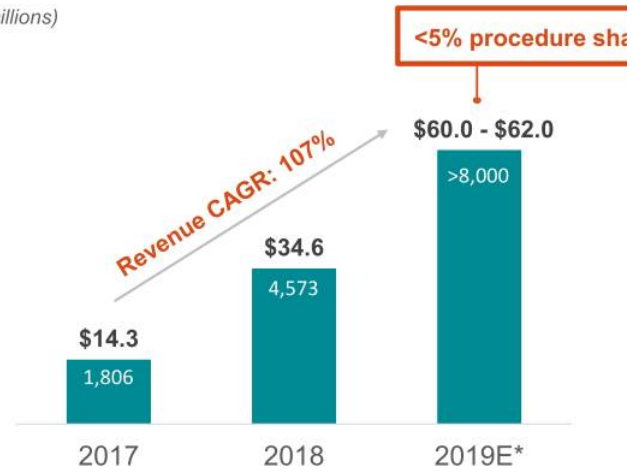


Solid Financial Profile

Quarterly Results¹ (\$ millions)



Annual Results² (\$ millions)



¹ Represents three-months ended June 30, 2019 compared to three-months ended June 30, 2018

² Represents twelve-months ended December 30, 2018 compared to twelve-months ended 30, 2017

³ Represents annual figure relative to total carotid procedures in 2018 of 168,000

*Represents the Company's publicly disclosed guidance as of July 29, 2019. This presentation should not be construed as an update to such guidance.

Well-Positioned for Long Term Growth



Built For Size and Scale

Proven Management Team



Erica Rogers

President & CEO

Med360, Visiogen, Boston Sci, Target



Lucas Buchanan

Chief Financial Officer

The Vertical Group, Medtronic, E&Y

Andrew Davis	EVP Global Sales & Marketing	Medtronic, Acelity, Boston Scientific
Richard Ruedy	EVP Clinical, Reg, Quality	Abbott, Nevro, Cardica, Acta
Alison Highlander	VP Human Resources	Roche, SRI, Atomic Tangerine
Bob Nicholas	VP Operations	Cardiokinetix, Stryker, Concentric, Heartport
Tammy Leitsinger	VP Med Affairs & Prof Education	Cordis, J&J
Mark Page	VP Marketing	Arstasis, Flowcardia, Boston Sci
Frances Versprille	VP Commercial Ops & Analytics	Cordis, Biocompatibles
Shari Rideout	VP Quality	Vital Connect, Cordis, Carbylan, Depuy/J&J

A New Era, A New Vascular Category

~\$2.6B US MARKET OPPORTUNITY

Carotid artery disease is a **multi-billion dollar category** with **one TCAR player** with the potential to become the **standard of care** for the last endovascular frontier

COMPELLING CLINICAL DATA

Safety, effectiveness and clinical advantages of TCAR have been observed in **multiple clinical trials and post-market studies**

TCAR-SPECIFIC REIMBURSEMENT

TCAR is **reimbursed under established codes and payment levels** and we are the **only company with transcarotid FDA labeling**

EFFICIENT COMMERCIAL MODEL

Concentrated hospital base and procedure volume combined with **easy-to-learn procedure** drives **efficient coverage model**

STRONG FINANCIAL PROFILE

Robust commercial ramp, compelling gross margins and significant operating leverage potential



APPENDIX
