UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

REGISTRATION STATEMENT
Under
The Securities Act of 1933

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2019
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For transition period from to
Commission File Number 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**20-8777622**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

1213 Innsbruck Dr. Sunnyvale, CA 94089, (408) 720-9002
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Erica J. Rogers
Chief Executive Officer
1213 Innsbruck Dr. Sunnyvale, CA 94089 (408) 720-9002
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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 7(a)(2)(B) of the Securities Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

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	SILK	Nasdaq Global Market

As of July 31, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 30,761,483.

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CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our plans to conduct further clinical trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected use of our products by physicians;
- our expectations regarding the number of procedures performed with our products, the number of physicians we expect to train, and the number of our sales territories;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- the expected growth of our business and our organization;
- our expected uses of the net proceeds from our initial public offering;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our ability to identify and develop new and planned products and/or acquire new products; and

- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Part I. Financial Information

Item 1: Unaudited Condensed Consolidated Financial Statements

Silk Road Medical, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share and per share data)	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 118,247	$ 24,990
Accounts receivable, net	5,417	4,520
Inventories	8,963	5,744
Prepaid expenses and other current assets	3,249	1,408
Total current assets	135,876	36,662
Property and equipment, net	2,743	2,880
Restricted cash	310	310
Other non-current assets	3,723	1,029
Total assets	$ 142,652	$ 40,881
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,189	$ 1,252
Accrued liabilities	8,299	7,586
Total current liabilities	9,488	8,838
Long-term debt	44,690	44,201
Redeemable convertible preferred stock warrant liability	—	16,091
Other liabilities	4,097	1,069
Total liabilities	58,275	70,199
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock issuable in series, $0.001 par value		
Shares authorized: None and 24,069,615 at June 30, 2019 and December 31, 2018, respectively		
Shares issued and outstanding: None and 21,233,190 at June 30, 2019 and December 31, 2018, respectively		
Liquidation preference: None and $121,144 at June 30, 2019 and December 31, 2018, respectively	—	105,235
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 and none at June 30, 2019 and December 31, 2018, respectively		
Shares issued and outstanding: none	—	—
Common stock, $0.001 par value		
Shares authorized: 100,000,000 and 29,879,220 at June 30, 2019 and December 31, 2018, respectively		
Shares issued and outstanding: 30,747,714 and 1,135,310 at June 30, 2019 and December 31, 2018, respectively	31	1
Additional paid-in capital	259,574	4,557
Accumulated deficit	(175,228)	(139,111)
Total stockholders' equity (deficit)	84,377	(134,553)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 142,652	$ 40,881

The accompanying notes are an integral part of these condensed consolidated financial statements.

Silk Road Medical, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

(in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ 14,928	$ 7,767	$ 27,694	$ 13,473
Cost of goods sold	3,697	2,391	7,035	4,325
Gross profit	11,231	5,376	20,659	9,148
Operating expenses:				
Research and development	3,113	2,326	5,820	4,426
Selling, general and administrative	14,135	7,816	28,001	14,135
Total operating expenses	17,248	10,142	33,821	18,561
Loss from operations	(6,017)	(4,766)	(13,162)	(9,413)
Interest income	598	24	650	37
Interest expense	(1,207)	(1,011)	(2,560)	(2,000)
Other income (expense), net	(5,333)	(1,898)	(21,045)	(1,682)
Net loss and comprehensive loss	$ (11,959)	$ (7,651)	$ (36,117)	$ (13,058)
Net loss per share, basic and diluted	$ (0.42)	$ (8.16)	$ (2.42)	$ (15.56)
Weighted average common shares used to compute net loss per share, basic and diluted	28,458,793	938,052	14,905,052	839,229

The accompanying notes are an integral part of these condensed consolidated financial statements.

Silk Road Medical, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

(in thousands, except share data)	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balances at December 31, 2018	21,233,190	$ 105,235	1,135,310	$ 1	$ 4,557	$ (139,111)	$ (134,553)
Exercise of stock options	—	—	251,305	—	375	—	375
Exercise of Series C preferred stock warrants	4,915	30	—	—	—	—	—
Employee stock-based compensation	—	—	—	—	241	—	241
Nonemployee stock-based compensation	—	—	—	—	21	—	21
Net loss and comprehensive loss	—	—	—	—	—	(24,158)	(24,158)
Balances at March 31, 2019	21,238,105	105,265	1,386,615	1	5,194	(163,269)	(158,074)
Exercise of stock options	—	—	176,576	1	363	—	364
Exercise of Series C preferred stock warrants	287,446	1,754	—	—	—	—	—
Exercise of common stock warrants	—	—	3,764	—	31	—	31
Net exercise of Series C preferred stock warrants upon IPO	1,653,004	37,121	—	—	—	—	—
Net exercise of common stock warrants upon IPO	—	—	2,204	—	—	—	—
Conversion of preferred stock to common stock upon IPO	(23,178,555)	(144,140)	23,178,555	23	144,117	—	144,140
Issuance of common stock in connection with IPO, net of underwriting discount, commissions and offering costs of $2,561	—	—	6,000,000	6	109,033	—	109,039
Employee stock-based compensation	—	—	—	—	814	—	814
Nonemployee stock-based compensation	—	—	—	—	22	—	22
Net loss and comprehensive loss	—	—	—	—	—	(11,959)	(11,959)
Balances at June 30, 2019	—	$ —	30,747,714	$ 31	$ 259,574	$ (175,228)	$ 84,377

The accompanying notes are an integral part of these condensed consolidated financial statements.

Silk Road Medical, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

(in thousands, except share data)	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	21,233,190	$ 105,235	663,270	$ 1	$ 2,977	$ (101,556)	$ (98,578)
Exercise of stock options	—	—	186,944	—	284	—	284
Employee stock-based compensation	—	—	—	—	164	—	164
Nonemployee stock-based compensation	—	—	—	—	(2)	—	(2)
Cumulative effect of change in accounting principle - ASC 606 adoption	—	—	—	—	—	87	87
Cumulative effect of change in accounting treatment - ASU 2016-09	—	—	—	—	13	(13)	—
Net loss and comprehensive loss	—	—	—	—	—	(5,408)	(5,408)
Balances at March 31, 2018	21,233,190	105,235	850,214	1	3,436	(106,890)	(103,453)
Exercise of stock options	—	—	106,732	—	148	—	148
Employee stock-based compensation	—	—	—	—	178	—	178
Nonemployee stock-based compensation	—	—	—	—	151	—	151
Net loss and comprehensive loss	—	—	—	—	—	(7,651)	(7,651)
Balances at June 30, 2018	21,233,190	$ 105,235	956,946	$ 1	$ 3,913	$ (114,541)	$ (110,627)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Silk Road Medical, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (36,117)	$ (13,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	350	131
Stock-based compensation expense	1,099	491
Change in fair value of redeemable convertible preferred stock warrant liability	21,030	1,678
Amortization of debt discount and debt issuance costs	22	46
Amortization of right-of-use asset	300	—
Non-cash interest expense	555	782
Provision for accounts receivable allowances	724	663
Provision for excess and obsolete inventories	43	—
Changes in assets and liabilities		
Accounts receivable	(1,622)	475
Inventories	(3,262)	(1,054)
Prepaid expenses and other current assets	(1,841)	(478)
Other assets	756	(52)
Accounts payable	(45)	24
Accrued liabilities	377	170
Other liabilities	(372)	244
Net cash used in operating activities	(18,003)	(9,938)
Cash flows from investing activities		
Purchases of property and equipment	(206)	(1,004)
Net cash used in investing activities	(206)	(1,004)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discount, commissions and offering costs paid	108,913	—
Proceeds from issuance of common stock	738	432
Proceeds from exercise of redeemable convertible preferred stock warrants	1,784	—
Proceeds from exercise of common stock warrants	31	—
Net cash provided by financing activities	111,466	432
Net change in cash, cash equivalents and restricted cash	93,257	(10,510)
Cash, cash equivalents and restricted cash, beginning of period	25,300	33,841
Cash, cash equivalents and restricted cash, end of period	$ 118,557	$ 23,331
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,982	$ 1,172
Non-cash investing and financing activities:		
Accounts payable and accrued liabilities for purchases of property and equipment	$ 7	$ 696
Landlord paid tenant improvements	$ —	794
Offering costs in accounts payable and accrued liabilities	$ 358	$ —
Right-of-use asset obtained in exchange for lease obligation	$ 3,982	$ —
Net exercise of convertible preferred stock warrants to preferred stock	$ 37,121	$ —
Conversion of convertible preferred stock to common stock upon initial public offering	$ 144,140	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Formation and Business of the Company

The Company

Silk Road Medical, Inc. (the “Company”) was incorporated in the state of Delaware on March 21, 2007. The Company has developed a technologically advanced, minimally-invasive solution for patients with carotid artery disease who are at risk for stroke. The Company's portfolio of TCAR products enable a new procedure, referred to as transcarotid artery revascularization, or TCAR, that combines the benefits of endovascular techniques and surgical principles. The Company manufactures and sells in the United States its portfolio of TCAR products which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. The Company commercialized its products in the United States in April 2016.

Reverse Stock Split

On March 13, 2019, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 2.7-for-1 reverse stock split of the Company's common stock and redeemable convertible preferred stock. The par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock, redeemable convertible preferred stock, stock options and warrants, and related per share amounts in the condensed consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split. The reverse stock split was effected on March 27, 2019.

Initial Public Offering

In April 2019, the Company issued and sold 6,000,000 shares of its common stock in its initial public offering (“IPO”) at a public offering price of $20.00 per share, for net proceeds of approximately $109,039,000 after deducting underwriting discounts and commissions of approximately $8,400,000 and expenses of approximately $2,561,000. Upon the closing of the IPO, all shares of redeemable convertible preferred stock then outstanding converted into shares of common stock and the Company's outstanding warrants to purchase shares of common and redeemable convertible preferred stock were exercised, or automatically net exercised absent a prior election. The exercises resulted in the reclassification of the fair value of the related redeemable convertible preferred stock warrant liability to additional paid-in capital.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or SEC, regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2018, and related disclosures, have been derived from the audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company’s annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company’s condensed consolidated financial information. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results

to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year.

The accompanying interim unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018 included in the Company's prospectus dated April 3, 2019 filed pursuant to Rule 424(b)(4) with the SEC on April 4, 2019.

Principles of Consolidation

Through December 17, 2018, the condensed consolidated financial statements of the Company include the accounts of Silk Road Medical, Inc. and its consolidated variable interest entity ("VIE"), NeuroCo, Inc. On December 17, 2018, the Company acquired all assets and assumed all liabilities of its VIE. As a result of the Merger, NeuroCo merged into the Company with the Company being the surviving corporation. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to the common stock valuation and related stock-based compensation, the valuation of the redeemable convertible preferred stock warrants, the valuation of deferred tax assets, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and the reserves for sales returns. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of June 30, 2019 and December 31, 2018. The carrying amounts of cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these instruments. Management believes that its borrowings bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value. Prior to its IPO, fair value accounting was applied to the redeemable convertible preferred stock warrant liability.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of June 30, 2019 and December 31, 2018, the Company's cash equivalents are entirely comprised of investments in money market funds.

Restricted cash as of June 30, 2019 and December 31, 2018 consists of a letter of credit of $310,000 representing collateral for the Company's facility lease.

Concentration of Credit Risk, and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the condensed consolidated balance sheet.

The Company's policy is to invest in money market funds, which are classified as cash equivalents on the condensed consolidated balance sheet. The Company's cash is held in Company accounts at two financial institutions and such amounts may exceed federally insured limits. The Company's money market funds are invested in highly rated money market funds.

The Company provides for uncollectible amounts when specific credit problems are identified. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts.

The Company's accounts receivable are due from a variety of health care organizations in the United States. At June 30, 2019 and December 31, 2018, no customer represented 10% or more of the Company's accounts receivable. For the three and six months ended June 30, 2019 and June 30, 2018, there were no customers that represented 10% or more of revenue.

The Company manufactures certain of its commercial products in-house. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers, the most significant of which is the ENROUTE stent. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payers to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this would have a material adverse impact on the Company.

Deferred Public Offering Costs

Specific incremental legal, accounting and other fees and costs directly attributable to a proposed or actual offering of securities may properly be deferred and charged against the gross proceeds of the offering. As of June 30, 2019 and December 31, 2018, there were $0 and $950,000, respectively, of offering costs primarily consisting of legal and accounting fees that were capitalized in other non-current assets on the condensed consolidated balance sheet.

Leases

The Company adopted ASC 842, "Leases," on January 1, 2019 and used the modified retrospective method for all leases not substantially completed as of the date of adoption and the package of practical expedients available in the standard. As a result of adopting ASC 842, the Company recorded an operating lease right-of-use ("ROU") asset of $3,982,000 included within other non-current assets and operating lease liabilities of $5,190,000 included within accrued liabilities and other liabilities on the condensed consolidated balance sheet related to its facility lease, based on the present value of the future lease payments on the date of adoption. The operating lease right-of-use asset also includes adjustments for prepayments and excludes lease incentives. The adoption did not have an impact on prior periods or on its condensed consolidated statements of operations and comprehensive loss.

In accordance with ASC 842, the disclosure impact of adoption on the condensed consolidated balance sheet were as follows (in thousands):

Balance Sheet:	Balance at December 31, 2018	Adjustments Due to ASC 842	Balance at January 1, 2019
Other non-current assets	$ —	$ 3,982	$ 3,982
Accrued liabilities	139	582	721
Other liabilities	1,069	3,400	4,469

The Company recognizes ROU assets and lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve months. The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the right-of-use asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company's leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments. The Company's considers renewal options in the determination of the lease term if the option to renew is reasonably certain. The Company has elected to account separately for contracts that contain lease and non-lease components consistent with its historical practice. Variable lease payments will be expensed as incurred.

Redeemable Convertible Preferred Stock Warrant Liability

Prior to its IPO, the Company accounted for its warrants for shares of redeemable convertible preferred stock as a liability based upon the characteristics and provisions of each instrument. Redeemable convertible preferred stock warrants classified as a liability were initially recorded at their fair value on the date of issuance and were subject to remeasurement at each subsequent balance sheet date. Any change in fair value as a result of a remeasurement was recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company recorded adjustments to the estimated fair value of the redeemable convertible preferred stock warrants until they were exercised in connection with its initial public offering in April 2019. At such time, the final fair value of the warrant liability was reclassified to stockholders' equity (deficit). The Company will no longer record any related periodic fair value adjustments.

Redeemable Convertible Preferred Stock

Prior to its IPO, the Company recorded its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs, and classified the redeemable convertible preferred stock outside of stockholders' equity (deficit) on the balance sheet as events triggering the liquidation preferences were not solely within the Company's control. Upon the closing of the Company's IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 23,178,555 shares

of common stock resulting in the reclassification of $144,140,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

Revenue Recognition

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers," using the modified retrospective method applied to contracts which were not completed as of that date. Revenue for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period revenue amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 605, "Revenue Recognition." Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue earlier for arrangements where the Company has satisfied its performance obligations but have not issued invoices. As of June 30, 2019 and December 31, 2018, the Company recorded $161,000 and $128,000, respectively, of unbilled receivables, which are included in accounts receivable, net on the condensed consolidated balance sheet, as the Company has an unconditional right to payment as of the end of the applicable period.

The Company's revenue is generated from the sale of its products to hospitals and medical centers in the United States through direct sales representatives. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company's products to its customers, either upon shipment of the product or delivery of the product to the customer under the Company's standard terms and conditions. The Company's products are readily available for usage as soon as the customer possesses it. Upon receipt, the customer controls the economic benefits of the product, has significant risks and rewards, and the legal title. The Company has present right to payment; therefore, the transfer of control is deemed to happen at a point in time. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring the goods.

For sales where the Company's sales representative hand delivers product directly to the hospital or medical center from the sales representative's trunk stock inventory, the Company recognizes revenue upon delivery, which represents the point in time when control transfers to the customer. Upon delivery there are legally-enforceable rights and obligations between the parties which can be identified, commercial substance exists and collectability is probable. For sales which are sent directly from the Company to hospitals and medical centers, the transfer of control occurs at the time of shipment or delivery of the product. There are no further performance obligations by the Company or the sales representative to the customer after delivery under either method of sale. As allowed under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed.

The Company is entitled to the total consideration for the products ordered by customers as product pricing is fixed according to the terms of customer contracts and payment terms are short. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Costs associated with product sales include commissions and royalties. The Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of revenue in the condensed consolidated statements of operations and comprehensive loss.

The Company accepts product returns at its discretion or if the product is defective as manufactured. The Company establishes estimated provisions for returns based on historical experience. The Company elected to expense shipping and handling costs as incurred and includes them in the cost of goods sold. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

Cost of Goods Sold

The Company manufactures certain of its portfolio of TCAR products at its facility and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and subassemblies, manufacturing overhead costs, direct labor, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalties.

Stock–Based Compensation

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") ASC 718, "Compensation-Stock Compensation." ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of all share-based payment option awards on the date of grant using an option pricing model. The fair value of stock options is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a straight-line basis. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions. The Company accounts for option forfeitures as they occur.

Income Taxes

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the condensed consolidated financial statements and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. As the Company has historically incurred operating losses, it has established a full valuation allowance against its net deferred tax assets, and there is no provision for income taxes.

The Company also follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes." ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded on the condensed consolidated financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock and warrants, and common stock options are considered to be potentially dilutive securities. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company’s redeemable convertible preferred stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

Net loss per share was determined as follows (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (11,959)	$ (7,651)	$ (36,117)	$ (13,058)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	28,458,793	938,052	14,905,052	839,229
Net loss per share, basic and diluted	$ (0.42)	$ (8.16)	$ (2.42)	$ (15.56)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	June 30,	
	2019	2018
Redeemable convertible preferred stock outstanding	—	21,233,190
Redeemable convertible preferred stock warrants outstanding	—	2,672,502
Common stock options	4,683,811	4,326,073
Common stock warrants outstanding	—	7,527
	4,683,811	28,239,292

Comprehensive Loss

For the three and six months ended June 30, 2019 and June 30, 2018, there was no difference between comprehensive loss and the Company's net loss.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. All of the Company's revenue was in the United States for the three and six months ended June 30, 2019 and June 30, 2018, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, ″Leases," that supersedes ASC 840, "Leases." Subsequently, the FASB issued several updates to ASU No. 2016-02, codified in ASC Topic 842 ("ASC 842"). The Company adopted ASC 842 on January 1, 2019 using the modified retrospective method for all leases not substantially completed as of the date of adoption. The Company elected to apply the package of practical expedients, which allowed the Company to not reassess: (i) whether expired or existing contracts contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing lease.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Statements." This update provides financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The update replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU No. 2016-13 is effective for public entities for annual periods beginning after December 15, 2019. The Company is evaluating the impact of adopting this guidance to its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement," which changed the disclosure requirements for fair value measurements by removing, adding and modifying certain disclosures. The standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance to its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, "Cloud Computing Arrangements," which aligns the requirements for capitalizing implementation costs in a Cloud Computing Arrangement service contract with the requirements for capitalizing implementation costs incurred for an internal-use software license. The standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance to its consolidated financial statements and related disclosures.

4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 – quoted prices in active markets for identical assets or liabilities;
- Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities;
- Level 3 – unobservable inputs.

The Company’s cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

In August 2014 through April 2016, the Company issued warrants to purchase 2,672,502 shares of Series C redeemable convertible preferred stock at the exercise price of $6.11 per share. As a derivative liability, the redeemable convertible warrants were initially recorded at fair value and were subject to remeasurement at each balance sheet date through the date of the Company's initial public offering in April 2019. Any change in fair value as a result of a remeasurement was recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company’s redeemable convertible warrant liability was classified within Level 3 of the fair value hierarchy.

At December 31, 2018, the fair value of the redeemable convertible warrant liability was determined by using an option pricing model to allocate the total enterprise value to the various securities within the Company's capital structure. As of December 31, 2018, the fair value of the redeemable convertible warrant liability was based on both the estimated fair value of the Company's common stock and on valuation models discounted at current implied market rates which are based on Level 3 inputs. Additionally, the model's inputs reflect assumptions that market participants would use in pricing the instrument in a current period transaction and included:

	December 31, 2018
Time to liquidity (years)	0.57
Expected volatility	62.5%
Discounted cash flow rate	12.0%
Risk-free interest rate	2.6%
Marketability discount rate	14%

The final fair value of the redeemable convertible warrants was remeasured on the date of the Company's initial public offering in April 2019. The final fair value of the redeemable convertible warrant liability was based on the estimated fair value of the Company's common stock at the time of its initial public offering. Subsequent to April 2019, there were no changes in fair value.

The following table sets forth the fair value of the Company's financial liabilities measured on a recurring basis as of December 31, 2018 (in thousands), as of June 30, 2019, there was no redeemable convertible warrant liability:

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Liabilities				
Redeemable convertible warrant liability	$ —	$ —	$ 16,091	$ 16,091

The changes in the redeemable convertible warrant liability are summarized below (in thousands):

Fair Value at December 31, 2018	$ 16,091
Change in fair value recorded in other income (expense), net	21,030
Reclassification upon IPO	(37,121)
Fair Value at June 30, 2019	$ —

There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2019 and 2018.

5. Balance Sheet Components

Inventories

Components of inventories were as follows:

(in thousands)	June 30, 2019	December 31, 2018
Raw materials	$ 866	$ 1,054
Finished products	8,097	4,690
Total	$ 8,963	$ 5,744

As of June 30, 2019 and December 31, 2018, there were no work-in-process inventories.

Accrued liabilities consist of the following:

(in thousands)	June 30, 2019	December 31, 2018
Accrued payroll and related expenses	$ 4,609	$ 5,157
Accrued professional services	1,024	1,014
Operating lease liability	730	—
Accrued royalty expense	389	313
Deferred revenue	257	137
Accrued travel expenses	443	270
Accrued clinical expenses	354	244
Accrued other expenses	493	451
Total	$ 8,299	$ 7,586

6. Long-term Debt

In October 2015, the Company entered into a term loan agreement with CRG. The term loan agreement provides for up to $30,000,000 in term loans split into two tranches as follows: (i) the Tranche A Loans provided for $20,000,000 in term loans, and (ii) the Tranche B Loans provided for up to $10,000,000 in term loans. The Company drew down the Tranche A Loans on October 13, 2015. The Tranche B Loans were available to be drawn prior to March 29, 2017. In January 2017, the term loan agreement was amended to extend the commitment period of the Tranche B Loans to April 28, 2017. In April 2017, the Company drew down $5,000,000 of the available Tranche B Loans.

In September 2018, the Company entered into Amendment No. 5 to the term loan agreement with CRG. Under the amended terms of the amended loan agreement the maturity date was extended to December 31, 2022 and the repayment schedule of the existing term loans were changed to interest only so that the outstanding principal amount of the term loans will be payable in a single installment at maturity. The related fixed interest rate was changed to equal 10.75% per annum, due and payable quarterly in arrears. At the election of the Company, 2.75% of the interest due and payable may be “paid in kind”, or PIK, and added to the then outstanding principal and 8.0% of the interest due and payable paid in cash. All unpaid principal, and accrued and unpaid interest, is due and payable in full on December 31, 2022. The amended term loan agreement also provided for additional term loans in an aggregate principal amount of up to $25,000,000. In September 2018, the Company drew down an additional $15,000,000 under the

term loan agreement with CRG. As provided for under the terms of the amended term loan agreement, the related fixed interest rate was further reduced to 10.00% upon the consummation of the Company's IPO in April 2019. Also, post consummation of the Company's IPO, 8.00% of the interest is due and payable in cash and at the election of the Company, 2.00% of the interest due and payable may be PIK.

The Company may voluntarily prepay the borrowings in full. The Tranche A borrowing required a payment, on the borrowing date, of a financing fee equal to 1.75% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 5.0% of the amounts borrowed plus any PIK is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the loan agreement. The borrowings are collateralized by a security interest in substantially all of the Company’s assets.

The Company is subject to financial covenants related to liquidity and minimum trailing revenue targets that begin in December 31, 2016 and are tested on an annual basis. The liquidity covenant requires the Company to maintain an amount which shall exceed the greater of (i) $3,000,000 and (ii) the minimum cash balance, if any, required of the Company by a creditor to the extent the Company has incurred permitted priority debt. The Company had to achieve minimum net revenue of $1,000,000 in 2016, $5,000,000 in 2017, $15,000,000 in 2018, and must achieve minimum net revenue of $30,000,000 in 2019 and $40,000,000 in 2020. The liquidity financial covenant has a 90-day equity cure period following end of the calendar year to issue additional shares of equity interests in exchange for cash, or to borrow permitted cure debt. In addition, the term loan agreement prohibits the payment of cash dividends on the Company’s capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the term loan agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the term loan agreement, the failure of the Company to adhere to the covenants set forth in the term loan agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of June 30, 2019, the Company was in compliance with all applicable financial covenants. As of June 30, 2019, management does not believe that it is probable that the above clauses will be triggered within the next twelve months, and therefore, the debt is classified as long-term on the condensed consolidated balance sheet.

In June 2019, the Company entered into Amendment No. 7 to the term loan agreement with CRG to reflect flexibility with respect to permitted cash equivalents.

The issuance costs and debt discount have been netted against the borrowed funds on the condensed consolidated balance sheet. The long-term debt balance as of June 30, 2019 was $44,690,000.

Future maturities under the term loan agreement as of June 30, 2019 are as follows (in thousands):

Period Ending December 31:	Amount
2019	$ 2,239
2020	4,454
2021	4,442
2022	48,256
	59,391
Add: Accretion of closing fees	1,040
	60,431
Less: Amount representing interest	(15,578)
Less: Amount representing debt discount and debt issuance costs	(163)
Present value of minimum payments	$ 44,690

In October 2015, CRG purchased 327,759 shares of the Company's Series C redeemable convertible preferred stock at $6.11 per share. In addition, CRG received warrants to purchase 163,877 shares of the Company's Series C redeemable convertible preferred stock. The warrants are immediately exercisable, at an exercise price per share of $6.11, and expire the earlier of October 2023 or upon the consummation of a change of control or initial public offering of the Company.

In July 2017, CRG purchased 163,877 shares of the Company's Series C convertible preferred stock at $6.11 per share.

7. Commitments and Contingencies

Operating Lease and Rights of Use

The Company's operating lease obligation consists of leased office, laboratory, and manufacturing space under a non-cancellable operating lease that expires in October 2024. Operating lease costs were $217,000 and $434,000 for the three and six months ended June 30, 2019, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $169,000 and $363,000 for the three and six months ended June 30, 2019, respectively. As of June 30, 2019, the weighted average discount rate was approximately 6.50% and the weighted average remaining lease term was 5.33 years. Balance sheet information as of June 30, 2019 consists of the following (in thousands):

Operating Lease:	June 30, 2019
Operating lease right-of-use asset in other non-current assets	$ 3,683
Operating lease liability in accrued liabilities	$ 730
Operating lease liability in other liabilities	4,097
Total operating lease liabilities	$ 4,827

The following table summarizes the Company's operating lease maturities as of June 30, 2019 (in thousands):

Period Ending December 31:	Amount
2019	$ 510
2020	1,037
2021	1,066
2022	1,096
2023	1,127
2024	904
Total lease payments	5,740
Less: imputed interest	(913)
Present value of lease liabilities	$ 4,827

Minimum future lease payments previously disclosed under ASC 840 in the Company's prospectus dated April 3, 2019 filed pursuant to Rule 424(b)(4) with the SEC on April 4, 2019 for the year ended December 31, 2018 are as follows (in thousands):

Year Ending December 31:	Total Minimum Lease Payments
2019	$ 1,002
2020	1,002
2021	1,031
2022	1,044
2023	1,920
	$ 5,999

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancellable commitments for inventory that were payable within one year to suppliers for purchases totaling $1,448,000 as of June 30, 2019.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is

minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of June 30, 2019.

Contingencies

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at June 30, 2019 and December 31, 2018.

Legal Matters

In February 2019, a former employee, through counsel, advised the Company that he had filed a charge of discrimination against the Company with the California Department of Fair Employment & Housing, or DFEH. The former employee's complaint alleges sexual harassment and retaliation in violation of the California Department of Fair Employment & Housing Act. The complaint does not allege specific damages. To date, the DFEH has not contacted the Company. The Company denies the complaint's allegations and intends to vigorously defend itself. No accrual was included in the Company's balance sheet as of June 30, 2019.

The Company and the former employee participated in mediation on July 30, 2019 and reached a settlement that requires the Company to pay an amount that is not material to its consolidated financial statements.

8. Redeemable Convertible Preferred Stock

The Company had the following redeemable convertible preferred stock issued and outstanding at December 31, 2018:

	December 31, 2018				
	Shares Authorized	Shares Issued and Outstanding	Per share Preference	Preferential Liquidation Value (in thousands)	Carrying Value (in thousands)
Series					
Series A	1,629,629	1,629,626	$ 2.70	$ 4,400	$ 4,369
Series A-1	1,111,111	1,111,109	$ 3.38	3,755	3,723
Series B	6,264,470	6,264,463	$ 6.11	38,276	38,014
Series C	15,064,405	12,227,992	$ 6.11	74,713	59,129
	24,069,615	21,233,190		$ 121,144	$ 105,235

Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into shares of common stock. As of June 30, 2019, the Company does not have any convertible preferred stock issued or outstanding.

Preferred Stock Warrants

Upon the closing of the IPO, all of the outstanding convertible preferred stock warrants were exercised, or net exercised based on the IPO price of $20.00 per share, into 1,945,365 shares of common stock.

As of June 30, 2019 and December 31, 2018, warrants to purchase an aggregate of 0 and 2,672,502, respectively, shares of Series C redeemable convertible preferred stock were outstanding.

9. Stockholders Equity (Deficit)

Preferred Stock

At June 30, 2019, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At June 30, 2019, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 30,747,714 shares were issued and outstanding. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of June 30, 2019, no dividends have been declared to date. Each share of common stock is entitled to one vote.

Common Stock Warrants

In connection with the IPO, the common stock warrants were cash, or net exercised based on the IPO price of $20.00 per share, into 5,968 shares of common stock. As of June 30, 2019 and December 31, 2018, warrants to purchase an aggregate of 0 and 7,527 shares of common stock were outstanding.

10. Stock Option Plans

In 2007, the Company established its 2007 Stock Option Plan which provided for the granting of stock options to employees, directors and consultants of the Company. In connection with its acquisition of NeuroCo in December 2018, the Company also assumed NeuroCo's 2015 Equity Incentive Plan, or the NeuroCo Plan. In March 2019, the Company's Board of Directors approved the termination of the 2007 Stock Option Plan and the NeuroCo 2015 Equity Incentive Plan and the adoption of the 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the Company's IPO. The 2019 Plan provides for the grant of ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were initially reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan will also include shares reserved but not issued under the 2007 Stock Option Plan, plus any share awards granted under the 2007 Stock Option Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan will also include an annual increase on the first day of each fiscal year beginning in fiscal 2020, equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. As of June 30, 2019, the Company has reserved 2,351,732 shares of common stock for issuance under the 2019 Plan.

The exercise price of ISOs and NSOs shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant, respectively, as determined by the Board of Directors. The exercise price of ISOs and NSOs granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors. To date, options have a term of 10 years and generally vest over 4 years from the date of grant.

Activity under the Company's 2007 Stock Option Plan and 2019 Plan is set forth below:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Balances, December 31, 2018	57,889	4,364,377	$ 3.79	7.36	$ 33,132
Authorized	2,317,000				
Options granted	(757,108)	757,108	$ 20.97		
Options exercised	—	(427,881)	$ 1.73		
Options cancelled	9,793	(9,793)	$ 3.99		
Balances, June 30, 2019	1,627,574	4,683,811	$ 6.76	7.50	$ 195,326
Vested and exercisable at June 30, 2019		2,493,493	$ 3.09	6.36	$ 113,136
Vested and expected to vest at June 30, 2019		4,383,811	$ 6.76	7.50	$ 195,326

The aggregate intrinsic value of options exercised during the six months ended June 30, 2019 was $9,077,000. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise.

2019 Employee Stock Purchase Plan

In March 2019, the Company's Board of Directors adopted the 2019 Employee Stock Purchase Plan, or 2019 ESPP, under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total of 434,000 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, beginning in 2020, by an amount equal to the lesser of (i) 1,200,000 shares (ii) 1.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2019 ESPP was effective upon adoption by the Company's Board of Directors but was not in use until the completion of the IPO in April 2019. The 2019 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended.

Stock-Based Compensation

The Company estimated the fair value of stock options using the Black–Scholes option pricing model. The fair value of employee and nonemployee stock options is being amortized on a straight–line basis over the requisite service period of the awards. The fair value of employee and nonemployee stock options was estimated using the following assumptions for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Expected term (in years)	5.00 - 6.25	5.00 - 6.25	5.00 - 6.25	5.00 - 6.25
Expected volatility	42.7% - 42.9%	38.0% - 38.1%	42.7% - 42.9%	38.0% - 38.1%
Risk-free interest rate	1.86% - 2.37%	2.71% - 2.74%	1.86% - 2.54%	2.68% - 2.74%
Dividend yield	—%	—%	—%	—%

As of June 30, 2019, there was total unrecognized compensation costs of $8,683,000 related to these stock options. These costs are expected to be recognized over a period of approximately 3.33 years.

The fair value of the shares to be issued under the Company's 2019 ESPP was estimated using the Black-Scholes valuation model with the following assumptions for the three months ended June 30, 2019:

	Three Months Ended June 30, 2019
Expected term (in years)	0.63
Expected volatility	47.8%
Risk-free interest rate	2.45%
Dividend yield	—%

Total stock-based compensation expense recognized during the three and six months ended June 30, 2019 and 2018, is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of goods sold	$ 54	$ 11	$ 69	$ 24
Research and development expenses	127	162	155	190
Selling, general and administrative expenses	655	156	875	277
	$ 836	$ 329	$ 1,099	$ 491

11. Subsequent Events

Public Offering of Common Stock

In August 2019, the Company completed a secondary public offering of 4,200,000 shares of its common stock sold by certain selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of its common stock from certain selling stockholders, at a public offering price

of $39.50 per share. The Company did not receive any of the proceeds from the sale of the shares of its common stock by the selling stockholders.

Item 2: Management Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected consolidated financial data" and our condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Quarterly Report on Form 10-Q entitled "Risk Factors."

Overview

We are a medical device company focused on reducing the risk of stroke and its devastating impact. We believe a key to stroke prevention is minimally-invasive and technologically advanced intervention to safely and effectively treat carotid artery disease, one of the leading causes of stroke. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care. We manufacture and sell in the United States our portfolio of TCAR products, which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque.

We began commercializing our products in the United States in late 2015. Our products are currently the only devices cleared and approved by the FDA specifically for transcarotid use. While our current commercial focus is on the U.S. market, our products have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We also intend to pursue regulatory clearances in China, Japan, and other select international markets. TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG, classifications.

We designed our commercial strategy and built our direct sales force with a particular focus on vascular surgery practices. Vascular surgeons are skilled in endovascular procedures, and our sales and marketing efforts are focused on driving adoption and supporting their practice development by offering them an innovative, safe, effective and minimally-invasive alternative for treating carotid artery disease. We also market to other specialists with experience in CEA or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. We consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products.

We manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We purchase our other products from third-party contract manufacturers, including our ENROUTE stent. Many of these third-party manufacturers and outside vendors are currently single-source suppliers. We expect that our existing manufacturing facility will be sufficient to meet our anticipated growth through at least the next four years.

Prior to our initial public offering, our primary sources of capital were private placements of convertible preferred stock, debt financing arrangements and revenue from sales of our products. Since inception, we have raised a total of $105.2 million in net proceeds from private placements of redeemable

convertible preferred stock ("convertible preferred stock"). As of June 30, 2019, we had cash and cash equivalents of $118.2 million, long-term debt of $44.7 million and an accumulated deficit of $175.2 million. In April 2019, we completed an initial public offering of six million shares. As a result of our initial public offering we received net proceeds of approximately $109.0 million, after underwriting discounts and commissions of approximately $8.4 million and other expenses associated with our initial public offering of approximately $2.6 million.

Key Business Metric - Number of U.S. TCAR procedures

We regularly review a number of operating and financial metrics, including the number of procedures performed in the United States, to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. The following table lists the number of procedures performed in each of the three month periods as indicated:

	Three Months Ended							
	March 31, 2017	**June 30, 2017**	**Sept. 30, 2017**	**Dec. 31, 2017**	**March 31, 2018**	**June 30, 2018**	**Sept. 30, 2018**	**Dec. 31, 2018**
Number of procedures	242	342	513	709	774	1,008	1,243	1,548

During the quarters ended March 31, 2019 and June 30, 2019, physicians performed over 1,700 procedures and approximately 2,000 procedures, respectively. We define a procedure as any instance in which our ENROUTE NPS is used and for which we have a record that the procedure was performed. A procedure that is started and then aborted, or converted to a different procedure, after the ENROUTE NPS is used would count as a procedure. The number of procedures is an indicator of our ability to drive adoption and generate revenue, and is helpful in tracking the progress of our business. We believe that it is representative of our current business; however, we anticipate this may be substituted for additional or different metrics as our business grows.

Components of our Results of Operations

Revenue

We currently derive all of our revenue from the sale of our portfolio of TCAR products to hospitals and medical centers in the United States. Our customers typically purchase an initial stocking order of our products and then reorder as needed. Each of our products is purchased individually, and the majority of our revenue is derived from sales of the ENROUTE NPS and ENROUTE stent. No single customer accounted for 10% or more of our revenue during the three and six months ended June 30, 2019 and 2018. We expect revenue to increase in absolute dollars as we expand our sales territories, new accounts and trained physician base and as existing physicians perform more TCAR procedures.

We expect our revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality. For example, in the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients, which results in fewer procedures.

Cost of Goods Sold and Gross Margin

We manufacture the ENROUTE NPS in California at our facility in Sunnyvale. We purchase our other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, direct labor, manufacturing overhead, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include

the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as those incurred for shipping our products and royalties related to the sale of our ENROUTE stent. We expense all inventory provisions as cost of goods sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production and ordering volumes increase and as we spread the fixed portion of our overhead costs over a larger number of units produced. We intend to use our design, engineering and manufacturing know-how and capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe over the long term, will reduce costs and have a positive impact on our gross margin. Our gross margin could fluctuate from quarter to quarter as we introduce new products, and as we adopt new manufacturing processes and technologies.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, medical affairs, and other costs associated with products and technologies that are in development. These expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, R&D expenses include costs associated with our clinical studies, including clinical trial design, clinical trial site initiation and study costs, data management, related travel expenses and the cost of products used for clinical trials, internal and external costs associated with our regulatory compliance and quality assurance functions and overhead costs. We expect R&D expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, commercial operations and analytics, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, training, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting, insurance and other expenses associated with being a public company.

Interest Income (Expense), net

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our term loan agreement. We may, at our election, pay the interest through a combination of cash and payment-in-kind, or PIK.

Other Income (Expense), net

Other income (expense), net primarily consists of gains and losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability at each balance sheet date. We recorded adjustments to the estimated fair value of the convertible preferred stock warrants until they were exercised in connection with our initial public offering in April 2019. At such time, the final fair value of the warrant liability was reclassified to stockholders' equity (deficit), we will no longer record any related periodic fair value adjustments.

Results of Operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
Revenue	$ 14,928	$ 7,767	$ 27,694	$ 13,473
Costs of goods sold	3,697	2,391	7,035	4,325
Gross profit	11,231	5,376	20,659	9,148
Operating expenses:				
Research and development	3,113	2,326	5,820	4,426
Selling, general and administrative	14,135	7,816	28,001	14,135
Total operating expenses	17,248	10,142	33,821	18,561
Loss from operations	(6,017)	(4,766)	(13,162)	(9,413)
Interest income (expense), net	(609)	(987)	(1,910)	(1,963)
Other income (expense), net	(5,333)	(1,898)	(21,045)	(1,682)
Net loss and comprehensive loss	$ (11,959)	$ (7,651)	$ (36,117)	$ (13,058)

Comparison of Three Months Ended June 30, 2019 and 2018

Revenue. Revenue increased $7.1 million, or 92%, to $14.9 million during the three months ended June 30, 2019, compared to $7.8 million during the three months ended June 30, 2018. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $1.3 million, or 55%, to $3.7 million during the three months ended June 30, 2019, compared to $2.4 million during the three months ended June 30, 2018. This increase was attributable to the increase in the number of products sold and additional manufacturing overhead costs as we invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the three months ended June 30, 2019 increased to 75%, compared to 69% in the three months ended June 30, 2018. Gross margin increased as our production and ordering volumes increased and we were able to spread the fixed portion of our overhead costs over a larger number of units produced, as well as manufacturing efficiencies and the delayed timing of certain manufacturing engineering projects.

Research and Development Expenses. R&D expenses increased $0.8 million, or 34%, to $3.1 million during the three months ended June 30, 2019, compared to $2.3 million during the three months ended June 30, 2018. The increase in R&D expenses was primarily attributable to an increase of $0.5 million in personnel-related expenses, including stock-based compensation, as we continue to support product development and clinical study programs, an increase of $0.2 million relating to educational grants, an

increase of $0.1 million in clinical and regulatory expense and an increase of $0.1 million in product development materials and costs, partially offset by a decrease in travel expenses.

Selling, General and Administrative Expenses. SG&A expenses increased $6.3 million, or 81%, to $14.1 million during the three months ended June 30, 2019, compared to $7.8 million during the three months ended June 30, 2018. The increase in SG&A costs was due to the continued commercialization of our products, marketing efforts and general corporate and other costs associated with operating as a public company. The increase in SG&A expenses is primarily attributable to an increase of $3.8 million in personnel-related expenses, an increase of $0.5 million in marketing, tradeshow and promotional costs, an increase of $0.4 million in consulting, legal and professional fees, an increase of $0.4 million in insurance costs, an increase of $0.4 million in travel expenses, an increase of $0.3 million in physician training and travel related costs, an increase of $0.3 million relating to depreciation and the allocation of facilities and related expenses, and an increase of $0.2 million in software related expense. Personnel-related expenses included stock-based compensation expense of $0.6 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.4 million, or 38%, to an expense of $0.6 million during the three months ended June 30, 2019, compared to an expense of $1.0 million during the three months ended June 30, 2018. This decrease in expense was attributable to an increase in interest income due to higher cash and cash equivalent balances, partially offset by additional interest expense associated with the $15.0 million of additional borrowings in September 2018 under our term loan agreement.

Other Income (Expense), Net. Other income (expense), net increased to an expense of $5.3 million during the three months ended June 30, 2019, compared to an expense of $1.9 million during the three months ended June 30, 2018. The increase was primarily attributed to the remeasurement of our convertible preferred stock warrants and recognition of the change in fair value.

Comparison of Six Months Ended June 30, 2019 and 2018

Revenue. Revenue increased $14.2 million, or 106%, to $27.7 million during the six months ended June 30, 2019, compared to $13.5 million during the six months ended June 30, 2018. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $2.7 million, or 63%, to $7.0 million during the six months ended June 30, 2019, compared to $4.3 million during the six months ended June 30, 2018. This increase was attributable to the increase in the number of products sold and additional manufacturing overhead costs as we invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the six months ended June 30, 2019 increased to 75%, compared to 68% in the six months ended June 30, 2018. Gross margin increased as our production and ordering volumes increased and we were able to spread the fixed portion of our overhead costs over a larger number of units produced.

Research and Development Expenses. R&D expenses increased $1.4 million, or 31%, to $5.8 million during the six months ended June 30, 2019, compared to $4.4 million during the six months ended June 30, 2018. The increase in R&D expenses was primarily attributable to an increase of $0.8 million in personnel-related expenses including stock-based compensation, an increase of $0.2 million in product development materials and costs, an increase of $0.2 million in clinical and regulatory expense, an increase of $0.2 million relating to educational grants, and an increase of $0.1 million in outside services, partially offset by a decrease in travel expenses.

Selling, General and Administrative Expenses. SG&A expenses increased $13.9 million, or 98%, to $28.0 million during the six months ended June 30, 2019, compared to $14.1 million during the six months ended June 30, 2018. The increase in SG&A costs was due to the continued commercialization of our products and general corporate and other costs associated with operating as a public company. The increase in SG&A expenses is primarily attributable to an increase of $8.5 million in personnel-related expenses, an increase of $1.5 million in consulting, legal and professional fees, an increase of $1.1 million in travel expenses, an increase of $0.7 million relating to depreciation and the allocation of facilities and related expenses, an increase of $0.6 million in physician training and travel related costs, an increase of $0.6 million in marketing, tradeshow and promotional costs, an increase of $0.5 million in insurance costs, and an increase of $0.4 million in software related expense. Personnel-related expenses included stock-based compensation expense of $0.8 million and $0.3 million for the three months ended June 30, 2019 and 2018, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.1 million, or 3%, to an expense of $1.9 million during the six months ended June 30, 2019, compared to an expense of $2.0 million during the six months ended June 30, 2018. This decrease in expense was attributable to an increase in interest income due to higher cash and cash equivalent balances, partially offset by additional interest expense associated with the $15.0 million of additional borrowings in September 2018 under our term loan agreement.

Other Income (Expense), Net. Other income (expense), net increased to an expense of $21.0 million during the six months ended June 30, 2019, compared to an expense of $1.7 million during the six months ended June 30, 2018. The increase was primarily attributed to the remeasurement of our convertible preferred stock warrants and recognition of the change in fair value.

Liquidity and Capital Resources

Prior to our initial public offering, our primary sources of capital were private placements of convertible preferred stock, debt financing agreements and revenue from the sale of our products. As of June 30, 2019, we had cash and cash equivalents of $118.2 million, an accumulated deficit of $175.2 million and $44.7 million outstanding under our term loan agreement. We believe that our existing cash and cash equivalents and expected revenue, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months.

Cash Flows

The following table summarizes our cash flows for each of the six months ended June 30:

	Six Months Ended June 30,	
(in thousands)	**2019**	**2018**
Net cash (used in) provided by:		
Operating activities	$ (18,003)	$ (9,938)
Investing activities	(206)	(1,004)
Financing activities	111,466	432
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 93,257	$ (10,510)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2019 was $18.0 million, consisting primarily of a net loss of $36.1 million and an increase in net operating assets of $6.0 million, partially offset by non-cash charges of $24.1 million. The increase in net operating assets was primarily due to an increase in accounts receivable, inventories and prepaid expenses and other current assets to

support the growth of our operations, partially offset by a decrease in other assets and increases in accrued and other liabilities, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation, stock-based compensation, provision for accounts receivable allowances, non-cash interest expense and other charges related to our term loan agreement, and an increase in the fair value of the convertible preferred stock warrants.

Net cash used in operating activities for the six months ended June 30, 2018 was $10.0 million, consisting primarily of a net loss of $13.1 million and an increase in net operating assets of $0.7 million, partially offset by non-cash charges of $3.8 million. The non-cash charges primarily consisted of depreciation, stock-based compensation, provision for accounts receivable allowances, non-cash interest expense and other charges related to our term loan agreement, and an increase in the fair value of the convertible preferred stock warrants.

Net Cash Used in Investing Activities

Net cash used in investing activities in the six months ended June 30, 2019 was $0.2 million consisting of purchases of property and equipment.

Net cash used in investing activities in the six months ended June 30, 2018 was $1.0 million consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2019 was $111.5 million, primarily attributable to proceeds of $108.9 million from our initial public offering, net of issuance costs paid, and proceeds from stock option exercises of $0.7 million and warrant exercises of $1.8 million.

Net cash provided by financing activities in the six months ended June 30, 2018 of $0.4 million relates to proceeds from the exercise of stock options.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

Contractual Obligations and Commitments

Our principal obligations consist of the operating lease for our facility, our term loan agreement and non-cancellable inventory purchase commitments. The non-cancellable purchase commitments primarily consist of ENROUTE stents and other inventory components.

There have been no material changes to our contractual obligations from those described in our final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on April 4, 2019.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may

be material. There have been no significant and material changes in our critical accounting policies during the three and six months ended June 30, 2019, as compared to those disclosed in “Management’s Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Estimates” in our final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on April 4, 2019.

Recently Issued Accounting Pronouncements

See Note 3 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for new accounting pronouncements not yet adopted as of the date of this Quarterly Report on Form 10-Q.

Item 3: Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

Credit Risk

As of June 30, 2019, our cash was maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe each to have sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Our cash equivalents are invested in highly rated money market funds.

Our accounts receivable primarily relate to revenue from the sale of our products to hospitals and medical centers in the United States. No customer represented 10% or more of our accounts receivable as of June 30, 2019.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective as described below.

However, our management, including our President and Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weaknesses in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Material Weakness in Internal Control Over Financial Reporting

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2017, we identified material weaknesses in our internal control over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We determined that we had material weaknesses because we did not maintain a sufficient complement of personnel with an appropriate degree of knowledge, experience, and training, commensurate with our accounting and reporting requirements. As a result, there were a number of post initial close adjustments that were material to the financial statements.

The second material weakness relates to the fact that we did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations, resulting in inappropriate segregation of duties over manual journal entries. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Management’s Plan to Remediate the Material Weaknesses

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in 2018. These efforts focused on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe the measures described above will remediate the material weaknesses identified and strengthen our internal control over financial reporting. These improvements to our internal control infrastructure were implemented in the fourth quarter of 2018, and were ongoing during the preparation of our financial statements for the three and six months ended June 30, 2019. As such, the remediation initiatives outlined above were not sufficient to fully remediate the material weaknesses in internal control over financial reporting as discussed above. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

Changes in Internal Control Over Financial Reporting

As described under the Management Plan to remediate the material weaknesses, we implemented changes to our internal control over financial reporting during the most recently completed fiscal quarter. There were no other changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Part II. Other Information

Item 1. Legal Proceedings

From time to time we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

In February 2019, a former employee, through counsel, advised us that he had filed a charge of discrimination against us with the California Department of Fair Employment & Housing, or DFEH. The former employee's complaint alleges sexual harassment and retaliation in violation of the California Department of Fair Employment & Housing Act. The complaint does not allege specific damages. To date, the DFEH has not contacted us. We deny the complaint's allegations and intend to vigorously defend ourselves. We have tendered the claim to our insurance carrier, and the carrier has appointed a law firm to represent us in this matter. We and the former employee participated in mediation on July 30, 2019 and reached a settlement that requires us to pay an amount that is not material to our consolidated financial statements.

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. Please also see "Cautionary Notes Regarding Forward-Looking Statements."

Risks Related to Our Business

We are an early-stage company with a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have a limited history operating as a commercial company.

We have incurred net losses since our inception in March 2007. For the years ended December 31, 2017 and 2018, we had a net loss of $19.4 million, and $37.6 million, respectively, and a net loss of $36.1 million for the six months ended June 30, 2019, and we expect to continue to incur additional losses in the future. As of June 30, 2019, we had an accumulated deficit of $175.2 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products that enable transcarotid artery revascularization, or TCAR. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure improvements.

We fully commercialized our products in the United States in 2016 and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue to devote a substantial amount of our resources to expand commercialization efforts and increase adoption of TCAR using our products, improve reimbursement for TCAR, and develop additional products. In addition, as a newly public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the

future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

We rely on, and currently sell products to enable, TCAR, a single and new procedure. We have limited commercial sales experience regarding TCAR, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

To date, all of our revenue has been derived, and we expect it to continue to be derived in the near term, from sales of our products that enable TCAR. TCAR is a new treatment option for certain patients diagnosed with carotid artery disease and, as a result, physician awareness of TCAR and our products, and experience with TCAR and our products, is limited. As a result, our products have limited product and brand recognition and TCAR has limited recognition within the medical industry. The novelty of TCAR and our products that enable the procedure, together with our limited commercialization experience, make it difficult to evaluate our current business and predict our future prospects. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- Physician and hospital demand for our products and adoption of TCAR, including the rate at which physicians recommend our products and TCAR to their patients;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products and TCAR or competing products and procedures;
- Any safety or effectiveness concerns that arise regarding our products or TCAR;
- Unanticipated delays in product development or product launches;
- Our ability to maintain our current or obtain further regulatory clearances or approvals;
- Delays in, or failure of, product and component deliveries by our third-party suppliers; and
- Introduction of new products or procedures for treating carotid artery disease that compete with our products.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

In addition, because we devote substantially all of our resources to our products that enable TCAR and rely on our products and the adoption of TCAR as our sole source of revenue, any factors that negatively impact our products or TCAR, or result in a decrease in sales of products, could have a material adverse effect on our business, financial condition and results of operations.

Our business is dependent upon the broad adoption of TCAR by hospitals and physicians.

To date, a substantial majority of our product sales and revenue have been derived from a limited number of hospitals and physicians who have adopted TCAR. Our future growth and profitability largely depend on our ability to increase physician awareness of TCAR and on the willingness of physicians to adopt our products and TCAR, and to recommend the procedure to their patients. Physicians may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery disease. Even if we are able to raise awareness among physicians, physicians tend to

be slow in changing their medical treatment practices and may be hesitant to select our products or TCAR for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell other products, such as stents and embolic protection devices for transfemoral carotid artery stenting, or CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Lack of experience with our products and concerns that we are relatively new to market;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- Reluctance to change to or use new products and procedures;
- Perceptions that our products are unproven; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with TCAR and our products.

Physicians play a significant role in determining the course of a patient's treatment for carotid artery disease and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing and education efforts primarily on vascular surgeons, and aim to educate referring physicians such as vascular surgeons, cardiologists, radiologists, neurologists, neurosurgeons and general practitioners regarding the patient population that would benefit from TCAR. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if diagnosing physicians that serve as the primary point of contact for patients are not made aware of TCAR, they may not refer patients to physicians for treatment using our products, and those patients may instead not seek treatment at all or may be treated with alternative procedures. In addition, some physicians may choose to utilize TCAR on only a subset of their total patient population or may not adopt TCAR at all. Further, as TCAR is a new procedure, it may not fit into the workstreams of certain physicians. If we are not able to effectively demonstrate that TCAR is beneficial in a broad range of patients, adoption of TCAR will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that TCAR or our products will achieve broad market acceptance among hospitals and physicians. Any failure of TCAR or our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of the Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we

are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.

The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's TCAR Surveillance Project contains real world data comparing procedures, we have not conducted head-to-head clinical trials to compare TCAR to the procedures historically available to patients, such as carotid endarterectomy, or CEA, or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis clinical trial is currently being conducted by the National Institutes of Health, which compares the effectiveness of each of CEA and CAS with best medical management solutions. Although enrollment is not expected to be completed until at least 2020, interim results could be released at any time. At the completion of the four-year follow-up, the trial could conclude that medical management alone achieves the same therapeutic results as surgical intervention, which would have an adverse impact on the adoption of TCAR. Finally, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, the interpretation of our clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition and results of operations.

As physicians are influenced by guidelines issued by physician organizations, such as the Society for Vascular Surgery, the rate of adoption of TCAR and sales of our products that facilitate the procedure is also heavily influenced by medical society recommendations. We believe the Society for Vascular Surgery's Clinical Practice Guidelines, or SVS Guidelines, are of particular importance to the broader market acceptance of TCAR. The most current SVS Guidelines on the management of carotid artery disease, published in 2011, do not specifically mention TCAR as a treatment for carotid artery disease, but generally discuss CAS and embolic protection methods, including flow reversal. If the next version of the SVS Guidelines do not recommend TCAR, or if the Society for Vascular Surgery issues a negative statement regarding TCAR, physicians may not adopt or continue to use TCAR or our products, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, if key opinion leaders who currently support TCAR cease to recommend TCAR or our products, our business, financial condition and results of operations will be adversely affected.

Adoption of TCAR depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of TCAR and adversely affect our business.

The success of TCAR depends in part on the skill of the physician performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our ENROUTE NPS and proper deployment of our ENROUTE stent. However, physicians rely on their previous medical training and experience when performing TCAR, and we cannot guarantee that all such physicians will have the necessary surgical skills to perform the procedure. We do not control which physicians perform TCAR or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to perform TCAR. If physicians perform TCAR in a manner that is inconsistent with its labeled indications, with components that are not our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of TCAR and our products that facilitate the procedure, which would have a material adverse effect on our business, financial condition and results of operations.

We have limited long-term data regarding the safety and effectiveness of our products, including our ENROUTE stent and TCAR generally.

Our products enable TCAR, which is a novel procedure, and our success depends on acceptance of our products and TCAR by the medical industry, including physicians and hospitals. The FDA reviews our products, and the stent manufactured for us by Cordis, for safety and effectiveness, prior to commercial launch of these products. Thereafter, physicians, through their own use of the products and evaluation of clinical data, make their own decisions as to whether our products are safe and effective for their patients and improve their clinical outcomes. Important factors upon which the effectiveness of our products, including our ENROUTE stent, will be measured are long-term data regarding the risk of stroke and death and the rate of restenosis following TCAR. The long-term clinical benefits of procedures that use our products are not known. We have limited data on the ENROUTE stent and TCAR up to one year. Any failure of our stent or in-stent restenosis of the carotid artery following deployment of the stent could deter physicians from adopting our products and could have a material adverse effect on our business, financial condition and results of operations.

The results of short-term clinical experience of our products do not necessarily predict long-term clinical benefit. We believe that physicians will compare the rates of long-term risk of stroke and death, as well as restenosis and reintervention for procedures using our products, against alternative procedures, such as CEA and CAS. If the long-term data do not meet physicians' expectations, or if long-term data indicate that our products are not as safe or effective as other treatment options or as current short-term data would suggest, our products may not become widely adopted, physicians may recommend alternative treatments for their patients and our business could be harmed.

If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage or delay payments, or if patients are left with significant out-of-pocket costs, it would have a material adverse effect on our business, financial condition and results of operations.

TCAR is currently covered under certain circumstances for certain patients by the Centers for Medicare and Medicaid Services, and has been covered by some commercial payers, independent networks and other entities not governed by the National Coverage Determination. In the United States, we derive our revenue from sales to hospitals and medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payers, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-payments. For example, our contracts are with the hospitals and medical centers that purchase our products for use with TCAR and not with the commercial payers. As a result, access to adequate coverage and reimbursement for our products by third-party payers is essential to the acceptance of our products by our customers.

However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third-party payers, so coverage and reimbursement can differ significantly from payer to payer, and each coverage decision and level of reimbursement is independent. As a result, third-party reimbursement may not be available or adequate for our products, and there is no guarantee that we will be able to maintain our current levels of coverage or reimbursement or be able to expand coverage to other insurance carriers. Further, payers continually review new technologies for possible coverage and can, without notice, deny coverage for products and procedures or delay coverage approval until further clinical data is available. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. If third-party reimbursement is not available or adequate for our products, or if there is any decline in the amount that payers are willing to reimburse our customers for our products, new customers may not adopt, or may reduce their rate of adoption of, our

products and we could experience additional pricing pressure for us, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our products are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers and on a medical necessity basis for certain patients covered by the Centers for Medicare and Medicaid Services. Based on reimbursement information regarding CEA and CAS, we estimate that approximately 75% of TCAR procedures are reimbursable by Medicare/Medicaid and approximately 25% are reimbursable by commercial payers. Current Procedure Terminology, or CPT, codes are developed and issued by the American Medical Association, or AMA. The U.S. Centers for Medicare & Medicaid Services, or CMS, determines Medicare payment based on formulas within the Medicare Resource-Based Relative Value Scale, which uses Relative Value Units, or RVUs. The RVU totals for a CPT code are determined and periodically updated by an AMA/Specialty Society RVS Update Committee, or RUC. In the future, reimbursement for our products may change based on a new RUC review. If the Society for Vascular Surgery recommended changes to the RVUs or declined to support the use of TCAR or the Medicare National Coverage Determination no longer covers TCAR, there would be a material adverse effect on our business, financial condition and results of operations. If this were to occur, commercial insurance companies could also adjust payment rates at which they reimburse our products. Other carotid artery disease treatments, such as CEA, may be more widely covered or subject to different co-pay policies and requirements. If patients are required to cover all or a part of the cost of our products out-of-pocket, they may be less likely to elect to use our products and/or undergo the procedure. Additionally, patients may elect to reduce or defer out-of-pocket costs during times of economic uncertainty or periods of legislative change. If hospital, physician and/or patient demand for TCAR, and thus our products that facilitate the procedure, is adversely affected by third-party reimbursement policies and decisions, it will have a material adverse effect on our business, financial condition and results of operations.

Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and reimbursement are not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Additionally, when payers combine their operations, the combined company may elect to reimburse for TCAR at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payers participating in the consolidation does not reimburse for TCAR at all, the combined company may elect not to reimburse for TCAR, which would adversely impact our business, financial condition and results of operations.

If we fail to comply with our obligations in our intellectual property license from Cardinal Health, we could lose license rights that are important to our business.

We are a party to a license agreement with Cordis Corporation, or Cordis, which was acquired by Cardinal Health, under which Cordis has granted us a worldwide, non-exclusive, royalty-bearing license to certain of its intellectual property related to the PRECISE® carotid stent for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. This license agreement imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Cardinal Health, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other

license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into a new license for a different stent. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors, including Cordis, to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

We rely on Cardinal Health to supply the ENROUTE stent, and if Cardinal Health fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.

We rely on Cardinal Health to manufacture the ENROUTE stent pursuant to a supply agreement between us and Cordis Corporation, which was acquired by Cardinal Health. We strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, and we estimate that it would take one to two years to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for another stent, and in each case qualify it for use with our other products. In addition, Cardinal Health currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. The current political and trade relationship between the United States and Mexico is strained and may deteriorate. If Cardinal Health's ability to manufacture the ENROUTE stent is interrupted as a result, or if Cardinal Health breaches its supply agreement with us, we may not have a sufficient number of stents for delivery to support TCAR procedures. Any shortfall in the supply of ENROUTE stents may result in lower adoption rates for TCAR, fewer TCAR procedures being performed generally, and a material adverse effect on our business, financial condition and results of operations.

TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption.

Risks of TCAR using our products include the risks that are common to endovascular procedures, including perforation, dissection, embolization, bleeding, infection, nerve injury and restenosis. Endovascular procedures occurring in the carotid arteries also include the additional risks of stroke, heart attack and death. We are aware of certain characteristics and features of TCAR that may prevent widespread market adoption, including the fact that physicians would need to adopt a new procedure, and that training for physicians will be required to enable them to effectively operate our products.

Our current products are contraindicated, and therefore should not be used, in certain patients. Our ENROUTE NPS is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients with uncorrected bleeding disorders; patients with severe disease of the ipsilateral common carotid artery; and patients with uncontrollable intolerance to flow reversal. Our ENROUTE stent is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients in whom the ENROUTE NPS is unable to be placed; patients with uncorrected bleeding disorders; patients with known allergies to nitinol; and patients with lesions in the ostium of the common carotid artery. Our ENHANCE peripheral access kit is contraindicated in patients with a known or suspected obstruction in the vessel. Our ENROUTE guidewire is contraindicated in patients judged not acceptable for percutaneous intervention. Additionally, patients that lack at least five centimeters of common carotid artery free of significant disease are not eligible for TCAR.

We have limited experience manufacturing our products in commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Sunnyvale, California, where we assemble, inspect, package, release and ship our products. We currently produce our ENROUTE NPS at this facility, and we do not have redundant facilities. If this facility suffers damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- Quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, the majority of which are our single source suppliers for the products they supply;
- Our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- Our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- Our failure to increase production capacity or volumes to meet demand;
- Our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- Difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.

We rely on single source suppliers for the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are relatively few

alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

Our dependence on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- Interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- Price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- Inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- Difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- Inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- Inability to ensure the quality of products manufactured by third parties;
- Production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- Delays in delivery by our suppliers due to changes in demand from us or their other customers.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience regarding TCAR, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated

changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which would impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

We have a limited total addressable market based on our current labeling restrictions.

The total addressable market for TCAR is limited by a number of factors. Approximately 168,000 patients with carotid artery disease in the United States received treatment in the form of surgical or endovascular intervention in 2018. Of this group, we estimate that approximately one-third would be outside the scope of the FDA-approved labeling for the ENROUTE stent, as those patients are not deemed to be at high risk for adverse events from CEA, or high surgical risk. The current FDA-approved labeling for the ENROUTE stent is limited to patients at high risk for adverse events from CEA. Patients at high risk for adverse events from CEA are defined as having significant comorbidities and/or anatomic risk factors, and/or advanced age, that would make them riskier candidates for CEA. Furthermore, the safety and effectiveness of TCAR has not been established for certain patients. For example, the FDA-cleared labeling for the ENROUTE NPS states that patients should have at least five centimeters of common carotid artery free of significant disease for initial access to the artery and positioning of the ENROUTE sheath. In addition, per the FDA-approved labeling for the ENROUTE stent, TCAR is limited to asymptomatic patients with carotid artery stenosis of at least 80% and symptomatic patients with carotid artery stenosis of at least 50%, both of which must also be high surgical risk. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions and severe vessel tortuosity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market.

Full penetration of the addressable market for TCAR is dependent upon labeling and reimbursement expansion initiatives.

The ENROUTE stent is not currently indicated for use in standard surgical risk patients. To access a larger portion of the market for carotid artery disease, we will need to obtain approval by the FDA for a label expansion of the ENROUTE stent in standard surgical risk patients and obtain corresponding reimbursement coverage expansion for TCAR. FDA approval of an ENROUTE stent label expansion will require additional data from clinical studies, which we intend to pursue. However, there are no guarantees that we will be able to obtain such clinical data or FDA approval of a label expansion for the ENROUTE stent, or that any label expansion or additional reimbursement coverage will be sufficient to access a significantly larger portion of the market for carotid artery disease patients. If we are unable to obtain labeling and reimbursement coverage expansion, it may have a material adverse effect on our business, financial condition and results of operations.

Changes in public health insurance coverage and government reimbursement rates for our products could affect the adoption of our products and our future revenue.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for TCAR could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

Any growth that we experience in the future will require us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

As demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

If our manufacturing facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce the products we manufacture or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

We currently maintain our research and development, manufacturing and administrative operations in a building located in Sunnyvale, California, which is situated on or near earthquake fault lines, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of materials and

components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current lease for our manufacturing facility expires in 2024, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

We have limited experience in training and marketing and selling our products, and if we fail in our training, to increase our sales and marketing capabilities or to develop broad brand awareness in a cost effective manner, our growth will be impeded and our business will suffer.

We have limited experience marketing and selling our products. We currently rely on our direct sales force to sell our products in targeted geographic regions, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in driving adoption of TCAR. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, our revenues and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our physician customer base and our business. Identifying and recruiting qualified sales and marketing personnel and training them on TCAR, on applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products, such as stents, that utilize independent third parties, which could place us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost effective manner is critical to achieving broad acceptance of our products and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments that are safer, more effective or gain greater acceptance

in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. We are initially positioning TCAR as an alternative in high risk patients to CEA and CAS. CEA has historically been performed by vascular surgeons as the primary surgical solution for carotid artery disease. The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Getinge / Maquet, Baxter, Terumo, Gore and Edwards. Some competitors market products for use in CAS, such as peripheral access kits, stents, distal filters, guidewires, balloons and sheaths. Such companies include Abbott, Boston Scientific, Cardinal Health, Medtronic, Terumo, Gore and InspireMD. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results. These companies enjoy several competitive advantages, including:

- Greater financial and human capital resources;
- Significantly greater name recognition;
- Established relationships with vascular surgeons, referring physicians, customers and third-party payers;
- Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- Established sales, marketing and worldwide distribution networks.

Because of the size of the market opportunity for the treatment of carotid artery disease, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New treatment options may be developed that could compete more effectively with our products due to the prevalence of carotid artery disease and the extensive research efforts and technological progress that exist within the market.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover

some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of the neck with the brain as the end organ is dangerous and presents risks of adverse events such as arterial dissection, cranial nerve injury, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales.

Our ability to compete depends on our ability to innovate successfully and deliver any new products in a timely manner.

The market for our products is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We are currently focused on development of existing products, but may devote additional resources to research in the future. If we are unable to develop new products, applications or features due to

constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

The failure of TCAR to meet patient expectations or the occurrence of adverse events from TCAR could impair our financial performance.

Our future success depends upon patients having an experience with TCAR that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as arterial restenosis or dissection, cranial nerve injury, wound complications, transient ischemic attacks, stroke, heart attack, and death. If the results of TCAR do not meet the expectations of the patients, or patients experience adverse events, it could discourage patients from referring TCAR to others. Dissatisfied patients may express negative opinions through social media. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Erica Rogers, our Chief Executive Officer, and Lucas Buchanan, our Chief Financial Officer, are essential to driving adoption of our products, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. In addition, the services of Andrew Davis, our Executive Vice President of Global Sales and Marketing, are critical to driving the growth in sales of our products. Any of our employees may terminate their employment with us at any time. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs, clinical operations and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. When we hire employees from competitors or other companies, their former employers have previously and may in the future attempt to assert that these employees or we have breached legal obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because w

e are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

Our products have been approved by the FDA for the treatment of high surgical risk patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke and death, potentially leading to product liability claims. Our products are not indicated for use in all patients with carotid artery disease, and therefore cannot be marketed or advertised in the United States for certain uses without additional clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing TCAR. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion.

In addition, if our products are defectively designed, manufactured or labeled, contains defective components or are misused, we may become subject to costly litigation initiated by physicians, hospitals or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

We may need substantial additional funding and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

We believe that our cash and cash equivalents as of June 30, 2019, expected revenue, and proceeds from our initial public offering in April 2019 will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of TCAR and our products;
- Whether we acquire third-party companies, products or technologies;
- Repayment of debt;

- The scope and timing of investment in our sales force;
- The scope, rate of progress and cost of our current or future clinical studies;
- The cost of our research and development activities;
- The cost and timing of additional regulatory clearances or approvals;
- The costs associated with any product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of June 30, 2019, we had an aggregate of approximately $44.7 million in principal and interest outstanding under our term loan agreement. We must make significant quarterly payments under the loan agreement, which has diverted and will continue to divert resources from other activities. Our obligations under the term loan agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, repurchase stock and make investments, in each case subject to certain exceptions. The covenants related to the term loan agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or

otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our term loan agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us, and any such assessments or obligations could adversely affect our business, financial condition and results of operations.

We have not historically collected sales and use, gross receipts, value added or similar taxes, although we may be subject to such taxes in various jurisdictions. One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country, or other jurisdiction that we should have been or should be collecting additional sales, use, or other taxes on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products, or otherwise harm our business, results of operations and financial condition.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $125.2 million and $115.8 million, respectively, which if not utilized will begin to expire in 2027 for U.S. federal purposes and 2028 for state purposes. We may use these NOLs to offset against taxable income

for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. Although we have not performed a formal 382 study, we believe we may have experienced at least one "ownership change." In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income or tax liability, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results.

As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our long-term strategy is to increase our international presence, including securing regulatory approvals in Japan and China. We have the right to affix the CE Mark to our products, allowing us to commercialize in Europe in the future. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payers. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;
- Obtaining regulatory clearance where required for TCAR in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;

- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customer's patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners, may be vulnerable to cyber attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business.

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of further enhancing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks

arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include

ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.

In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not

provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad,

which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a “first-to-invent” system to a “first-to-file” system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

Risks Related to Government Regulation

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- Imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;
- Established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- Expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and the expansion in the government's role in the U.S. healthcare industry may result in decreased sale of our products and, lower reimbursement by payers for our products, all of which may have a material adverse effect on our business, financial condition and results of operations. The Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. They could result in reduced demand for our products or result in additional pricing pressure. Any such reforms could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition and results of operations. Changes and reforms in the European Union could have similar effects.

Changes in the CMS fee schedules may harm our revenue and operating results.

Government payers, such as Centers for Medicare and Medicaid Services, or CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and

administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with broad based healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- Federal and state laws and regulations regarding billing and claims payment applicable to TCAR and regulatory agencies enforcing those laws and regulations;
- FDA prohibitions against the advertisement, promotion and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- The federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the CMS programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in mandatory exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- The federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;

- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- The FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- The federal Physician Payment Sunshine Act, or Open Payments, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, and its implementing regulations, which requires manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to licensed physicians, certain other healthcare professionals, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Our failure to submit required information on time may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Failure to comply with the HIPAA privacy and security standards when applicable can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and
- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. Any action brought

against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide ranging and govern, among other things:

- Product design, development and manufacture;
- Laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- Premarketing clearance or approval;
- Record keeping;
- Product marketing, promotion and advertising, sales and distribution; and
- Post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling

data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- Our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- An advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- The applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers;
- The potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- The FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA and European Union regulatory authorities strictly regulate the labeling, promotion and advertising of our products, including comparative and superiority claims vis a vis competitors' products, that may be made about products.

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data

for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at a minimum of 30 sites in the United States to evaluate the safety and effectiveness of our products in at least 600 subjects. We have completed enrollment in this study and we are in the process of submitting data to the FDA. Thereafter, the product labeling must be updated and submitted in a PMA supplement, including any adverse event data, from the post-approval study. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as “for cause” inspections, of our business, sites and facilities as part of its review process. We recently identified the need to implement corrective actions to our complaint handling procedures, which may have caused a delay in timely submission of 20 MDR reports to the FDA since we began commercialization in 2015. As of July 31, 2019, we had filed 96 MDR reports with the FDA for adverse events including stroke, arterial dissection, stent thrombosis and wound complications.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity, warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- Adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Denial of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

- Withdrawal of 510(k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.

We may be required to conduct clinical studies that demonstrate competent and reliable evidence that our products are safe and effective before we can commercialize our products. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our products for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our products. Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

Material modifications to our products may require new 510(k) clearances, premarket approval, or CE Marks, or may require us to recall or cease marketing our products until new clearances or approvals are obtained.

Material modifications to the intended use or technological characteristics of our products will require new 510(k) clearances, premarket approvals or CE Marks prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

If we, or our suppliers, fail to comply with the FDA's QSR or the European Union's Medical Device Directive, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the FDA's Quality System Regulation, or QSR, and the European Union's Medical Device Directive, or MDD, both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service, to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health, or CDPH, and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

We can provide no assurance that we will continue to remain in material compliance with the QSR or MDD. If the FDA, CDPH or our notified body in the European Union, the British Standards Institution, or BSI, inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility we may be unable to produce our products, which would harm our business.

With the transition from the MDD to the new European Union Medical Device Regulation, or MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law, which is effective in May 2020. Should our notified body fail to obtain such designation or the scope of their designation does not include our product category, then our ability to apply the CE mark and commercialize in the European Union may be interrupted. Identification and engagement of a new and properly designated notified body is a time consuming process that may require comprehensive quality system audits and new conformity assessment certifications for our products.

The impact of the new EU Medical Device Regulation may be costly and disruptive to our business.

In 2017, the European Union released new regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in-vitro diagnostics that will go into effect over a three-year period from 2020 to 2022. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Major changes include:

- Reclassification of some products;
- Greater emphasis on clinical data;
- Data transparency, including publication of clinical trial data and safety summaries;
- Defined content and structure for technical files to support registration;
- Unique device identification system;
- Greater burden on post-market surveillance and clinical follow-up;
- Reduction of adverse event reporting time from 30 to 15 days after the event; and
- More power to notified bodies.

Complying with these new regulations may result in Europe being less attractive as a “first market” destination. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated. Adjusting to the new Medical Device Regulation may prove to be costly and disruptive to our business.

Our products may in the future be subject to product recalls that could harm our reputation.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our products would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would also negatively affect our stock price.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- Changes in reimbursement by current or potential payers;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up and other legal restrictions on resale, the trading price of our common stock could decline. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of an aggregate of 18,637,294 shares of our outstanding common stock, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of July 31, 2019, our directors, officers and each stockholder holding 5% or more of our outstanding common stock and their affiliates beneficially owned approximately 71.7% of our outstanding common stock in the aggregate. In addition, we are required to nominate and use commercially reasonable efforts to have a number of individuals proportionate to the number of shares of common stock held by entities affiliated with Warburg Pincus & Co. and Vertical Group, L.P. compared to the number of shares of common stock outstanding, designated by each of Warburg Pincus & Co. and entities affiliated with the Vertical Group, L.P., elected to the board of directors. As a result, the above stockholders, if they act together, and Warburg Pincus & Co., acting alone, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. We have not elected under the rules of the Nasdaq Stock Market to take advantage of the "controlled company" exemption to opt out of any corporate governance requirements, but this concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

We have previously identified two material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Prior to the completion of our initial public offering, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the year ended December 31, 2017, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We determined that we had a material weakness because we did not maintain a sufficient complement of personnel with an appropriate degree of knowledge, experience, and training, commensurate with our accounting and reporting requirements. As a result, there were a number of post initial close adjustments that were material to the financial statements.

The second material weakness relates to the fact that we did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations, resulting in inappropriate segregation of duties over manual journal entries. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in 2018. These efforts focused on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe the measures described above will remediate the material weaknesses identified and strengthen our internal control over financial reporting. These improvements to our internal control infrastructure were implemented in the fourth quarter of 2018, and were ongoing during the preparation of our financial statements for the three and six months ended June 30, 2019. As such, the remediation initiatives outlined above were not sufficient to fully remediate the material weaknesses in internal control over financial reporting as discussed above. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

While we continue to implement our plan to remediate the material weaknesses, we cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate these deficiencies in internal control or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements, causing us to fail to meet our reporting obligations.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting for the year ended D

ecember 31, 2020. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

We are continuing the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are an “emerging growth company” and a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.

We currently qualify as an “emerging growth company” under the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual revenue of more than $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer,

which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- A classified board of directors;
- Advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- A supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- The right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- Allowing stockholders to remove directors only for cause;
- A requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- Allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- A requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- Limiting the forum to Delaware for certain litigation against us; and
- Limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president, in the absence of a chief executive officer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. See "Description of Capital Stock."

Our amended and restated certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted

by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against the company or any director or officer of the company arising pursuant to any provision of the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware or federal court located within the State of Delaware if the Court of Chancery does not have jurisdiction, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. A complaint asserting a cause of action under the Securities Act may be brought in state or federal court. With respect to the Securities Exchange Act of 1934, or Exchange Act, only claims brought derivatively under the Exchange Act would be subject to the forum selection clause described above. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in such action. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings and other factors our board of directors may deem relevant. In addition, our loan agreement limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

Our chief financial officer had not previously been the chief financial officer of a publicly traded company and our chief executive officer had not previously been the chief executive officer of a publicly traded company. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. We are required, pursuant to Section 404, to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report after the completion of our initial public offering in April 2019, provide a management report on the internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial re

porting from our independent registered accounting firm. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are implementing the process and documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from Public Offering of Common Stock

Our initial public offering of 6,000,000 shares of common stock was effected through a registration statement on Form S-1 (File No. 333-230045), which was declared effective on April 3, 2019 and pursuant to which we sold an aggregate 6,000,000 shares of our common stock at a public offering price of $20.00 per share for an aggregate offering price of $120.0 million. On April 4, 2019, the underwriters fully exercised their option to purchase 900,000 additional shares of common stock from the selling stockholders pursuant to the underwriting agreement. When our initial public offering closed on April 8, 2019, we received net proceeds of approximately $109.0 million, after deducting underwriting discounts and commissions of approximately $8.4 million and other expenses of approximately $2.6 million. No payments for such expenses were made directly or indirectly to any of our officers or directors or persons holding 10 percent or more of our securities.

J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated acted as representatives of the underwriters for the offering. There has been no material change in the planned

use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on April 4, 2019 pursuant to Rule 424(b) of the Securities Act.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibit Index

The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

		Incorporated by Reference			
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1**	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the registrant as currently in effect.	S-1	333-230045	3.3	3/4/2019
3.2**	Bylaws of the registrant as currently in effect.	S-1	333-230045	3.5	3/4/2019
4.1**	Specimen Common Stock Certificate of the registrant.	S-1/A	333-230045	4.1	3/25/2019
4.2**	Amended and Restated Registration Rights Agreement by and among the registrant and certain stockholders, dated July 7, 2017.	S-1	333-230045	4.2	3/4/2019
4.3**	Amended and Restated Stockholders Agreement by and among the registrant and certain stockholders, dated July 7, 2017.	S-1	333-230045	4.3	3/4/2019
4.4**	Amendment to the Amended and Restated Registration Rights Agreement, dated March 21, 2019.	S-1/A	333-230045	4.8	3/25/2019
10.1**	Form of Indemnification Agreement for directors and executive officers.	S-1	333-230045	10.1	3/4/2019
10.2+**	2007 Stock Plan, as amended, and related form agreement.	S-1	333-230045	10.2	3/4/2019
10.3+**	2019 Employee Stock Purchase Plan and related form agreements.	S-1/A	333-230045	10.4	3/25/2019
10.4+**	Executive Incentive Compensation Plan.	S-1/A	333-230045	10.5	3/25/2019
10.5+**	2019 Equity Incentive Plan and related form agreements.	S-1/A	333-230045	10.6	3/25/2019
10.6#**	Supply Agreement by and between the registrant and Cordis Corporation, dated October 21, 2011, as amended by the Amendment dated March 12, 2012, the Second Amendment to Supply Agreement dated July 12, 2012, the Third Amendment to Supply Agreement dated April 19, 2013 and the Fourth Amendment to Supply Agreement dated April 9, 2018.	S-1	333-230045	10.6	3/4/2019
10.7#**	License Agreement by and between the registrant and Cordis Corporation, dated December 17, 2010.	S-1	333-230045	10.7	3/4/2019
10.8**	Quality Assurance Agreement by and among the registrant and Lake Region Medical and affiliates, dated May 4, 2015.	S-1	333-230045	10.8	3/4/2019
10.9#**	Amended and Restated Manufacturing and Supply Agreement by and between the registrant and Galt Medical Corporation, dated January 10, 2018.	S-1	333-230045	10.9	3/4/2019

10.10**	Term Loan Agreement by and among the registrant, certain affiliates of CRG Partners III L.P. as lenders and certain subsidiary guarantors, dated October 13, 2015, as amended by Amendment No. 1 to Term Loan Agreement dated January 3, 2017, Amendment No. 2 to Term Loan Agreement dated June 22, 2017, Amendment No. 3 to Term Loan Agreement dated November 30, 2017, Amendment No. 4 to Term Loan Agreement dated June 25, 2018, Amendment No. 5 to Term Loan Agreement dated September 4, 2018, and Amendment No. 6 to Term Loan Agreement dated November 14, 2018 and effective as of October 31, 2018.	S-1	333-230045	10.10	3/4/2019
10.11**	Lease Agreement by and between the registrant and Hanover Properties Ltd., dated November 30, 2017.	S-1	333-230045	10.11	3/4/2019
10.12**	Director Offer Letter for Donald Zurbay dated as of February 6, 2018.	S-1/A	333-230045	10.13	3/25/2019
10.13+**	Confirmatory Employment Letter between the registrant and Erica Rogers, dated as of March 21, 2019.	S-1/A	333-230045	10.14	3/25/2019
10.14+**	Confirmatory Employment Letter between the registrant and Lucas Buchanan, dated as of March 21, 2019.	S-1/A	333-230045	10.15	3/25/2019
10.15+**	Confirmatory Employment Letter between the registrant and Richard Ruedy, dated as of March 21, 2019.	S-1/A	333-230045	10.16	3/25/2019
10.16+**	Confirmatory Employment Letter between the registrant and Andrew Davis, dated as of March 21, 2019.	S-1/A	333-230045	10.17	3/25/2019
10.17+**	Change in Control and Severance Agreement between the registrant and Erica Rogers, dated as of March 21, 2019.	S-1/A	333-230045	10.18	3/25/2019
10.18+**	Change in Control and Severance Agreement between the registrant and Lucas Buchanan, dated as of March 21, 2019.	S-1/A	333-230045	10.19	3/25/2019
10.19+**	Change in Control and Severance Agreement between the registrant and Richard Ruedy, dated as of March 21, 2019.	S-1/A	333-230045	10.20	3/25/2019
10.20+**	Change in Control and Severance Agreement between the registrant and Andrew Davis, dated as of March 21, 2019.	S-1/A	333-230045	10.21	3/25/2019
31.1*	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document. The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.
** Previously filed.
\+ Indicates management contract or compensatory plan.
\# Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted information has been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

SILK ROAD MEDICAL, INC.

August 13, 2019 By: /s/ Erica J. Rogers

Erica J. Rogers
President, Chief Executive Officer and Director (principal executive officer)

August 13, 2019 By: /s/ Lucas W. Buchanan

Lucas W. Buchanan
Chief Financial Officer (principal financial officer and principal accounting officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Erica J. Rogers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Silk Road Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Erica J. Rogers

Erica J. Rogers
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 13, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Lucas W. Buchanan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Silk Road Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Lucas W. Buchanan

Lucas W. Buchanan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 13, 2019

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Silk Road Medical, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), Erica J. Rogers, as Chief Executive Officer of the Company, and Lucas W. Buchanan, as Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Erica J. Rogers

Erica J. Rogers
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 13, 2019

/s/ Lucas W. Buchanan

Lucas W. Buchanan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 13, 2019

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Silk Road Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.