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

FORM 10-Q

(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, 2023

OR

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

For the transition period from to
Commission File Number: 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8777622**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1213 Innsbruck Dr., Sunnyvale, CA 94089
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (408) 720-9002

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, $0.001 par value	SILK	Nasdaq Stock Market LLC

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 13(a) of the Exchange Act. ☐

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

As of July 31, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 38,832,992.

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As used in this report, references to “Silk Road Medical,” the “Company,” “we,” “our” or “us,” unless the context otherwise requires, refer to Silk Road Medical, Inc.

“Silk Road Medical,” the “Silk Road Medical” logo, “TCAR,” “ENROUTE,” the “ENROUTE” logo, “ENHANCE,” “Enflate” and our other registered or common law trade names, trademarks or service marks appearing in this Quarterly Report on Form 10-Q are our property. Trade names, trademarks and service marks of other companies appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies unless otherwise stated. Solely for convenience, the trademarks and tradenames referred to in this Quarterly Report on Form 10-Q appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

CAUTIONARY NOTE 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 within the meaning of the federal securities laws and are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. 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, or the use of future dates.

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

- our goal to establish transcarotid artery revascularization, or TCAR, as the standard of care for the treatment of carotid artery disease;
- our 2023 strategic priorities to grow, strengthen and diversify our business;
- our plans to conduct further clinical trials and anticipated enrollment, clinical sites, completion, results and timing thereof;
- our plans and expected timeline related to our products, including timing of commercial launch, or developing new products, to address additional indications or to obtain regulatory approvals or clearances or otherwise;
- the expected use of our products by physicians, including market awareness, acceptance and adoption of our products and anticipated increased utilization of our products and market penetration;
- our expectations regarding the number of procedures that will be 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 current products and any new products we create;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payer coverage and reimbursement and the anticipated effect of such decisions;
- our ability to retain and recruit key personnel, including the continued expansion of our sales and marketing infrastructure, and the anticipated effect of such actions;
- 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 and the sufficiency of our current manufacturing capabilities;
- our ability to obtain and maintain intellectual property protection for our products and our business;
- our ability to expand our business into new geographic markets and the anticipated timing thereof, including in Japan and China;
- our compliance with extensive Nasdaq and U.S. Securities and Exchange Commission, or SEC, requirements and government laws, rules and regulations both in the United States and internationally;

- our expectations regarding operating trends, future financial performance and expense management and our estimates of our future expenses, ongoing losses, future revenue, including per procedure revenue and the effect thereon of new products, gross margins, operating leverage, capital requirements and our need for, or ability to obtain, additional financing;
- our ability to identify and develop new and planned products and/or acquire new products;
- our expectations regarding operating in a more normal health care operating environment;
- our experience with inflationary and price pressures and increased labor costs and labor and staffing shortages;
- developments and projections relating to our market opportunity and penetration, competitors or our industry; and
- our intended use of net proceeds from our public offerings.

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 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 changes in our expectations. 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.

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: Condensed Financial Statements

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

(in thousands, except share and per share data)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 28,400	$ 55,358
Short-term investments	159,961	158,316
Accounts receivable, net	21,525	18,007
Inventories	19,067	19,293
Prepaid expenses and other current assets	4,543	3,924
Total current assets	233,496	254,898
Long-term investments	13,884	—
Property and equipment, net	8,644	9,372
Restricted cash	—	155
Other non-current assets	7,336	5,260
Total assets	$ 263,360	$ 269,685
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,338	$ 2,523
Accrued liabilities	18,759	21,965
Total current liabilities	24,097	24,488
Long-term debt	75,104	74,596
Other liabilities	8,654	6,726
Total liabilities	107,855	105,810
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 at June 30, 2023 and December 31, 2022		
Shares issued and outstanding: none at June 30, 2023 and December 31, 2022		
Common stock, $0.001 par value	—	—
Shares authorized: 100,000,000 at June 30, 2023 and December 31, 2022		
Shares issued and outstanding: 38,812,280 and 38,355,972 at June 30, 2023 and December 31, 2022, respectively	39	38
Additional paid-in capital	529,453	507,715
Accumulated other comprehensive loss	(331)	(166)
Accumulated deficit	(373,656)	(343,712)
Total stockholders' equity	155,505	163,875
Total liabilities and stockholders' equity	$ 263,360	$ 269,685

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

Silk Road Medical, Inc.
Condensed 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,	
	2023	2022	2023	2022
Revenue	$ 45,298	$ 33,173	$ 85,429	$ 61,193
Cost of goods sold	13,004	9,012	25,530	17,588
Gross profit	32,294	24,161	59,899	43,605
Operating expenses:				
Research and development	10,780	10,655	21,213	18,778
Selling, general and administrative	35,830	27,700	69,913	54,975
Total operating expenses	46,610	38,355	91,126	73,753
Loss from operations	(14,316)	(14,194)	(31,227)	(30,148)
Interest income	2,434	122	4,721	134
Interest expense	(1,712)	(1,031)	(3,405)	(1,652)
Loss on debt extinguishment	—	(245)	—	(245)
Other income (expense), net	110	(50)	(33)	(166)
Net loss	(13,484)	(15,398)	(29,944)	(32,077)
Other comprehensive loss:				
Change in unrealized loss on investments, net	(414)	(2)	(165)	(2)
Other comprehensive loss	(414)	(2)	(165)	(2)
Net loss and comprehensive loss	$ (13,898)	$ (15,400)	$ (30,109)	$ (32,079)
Net loss per share, basic and diluted	$ (0.35)	$ (0.44)	$ (0.77)	$ (0.91)
Weighted average common shares used to compute net loss per share, basic and diluted	38,765,166	35,143,178	38,649,327	35,083,569

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

Silk Road Medical, Inc.
Condensed Statements of Stockholders' Equity
(unaudited)

(in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balances at December 31, 2022	38,355,972	$ 38	$ 507,715	$ (343,712)	$ (166)	$ 163,875
Exercise of stock options	144,474	—	1,110	—	—	1,110
Issuance of common stock upon vesting of restricted stock units	207,995	1	—	—	—	1
Stock-based compensation	—	—	8,838	—	—	8,838
Net loss	—	—	—	(16,460)	—	(16,460)
Unrealized gain on investments, net	—	—	—	—	249	249
Balances at March 31, 2023	38,708,441	39	517,663	(360,172)	83	157,613
Exercise of stock options	32,483	—	232	—	—	232
Issuance of common stock upon vesting of restricted stock units	19,400	—	—	—	—	—
Issuance of common stock under employee purchase plan	51,956	—	1,359	—	—	1,359
Stock-based compensation	—	—	10,199	—	—	10,199
Net loss	—	—	—	(13,484)	—	(13,484)
Unrealized loss on investments, net	—	—	—	—	(414)	(414)
Balances at June 30, 2023	38,812,280	$ 39	$ 529,453	$ (373,656)	$ (331)	$ 155,505

(in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balances at December 31, 2021	34,980,896	$ 35	$ 367,907	$ (288,702)	$ —	$ 79,240
Exercise of stock options	35,453	—	168	—	—	168
Issuance of common stock upon vesting of restricted stock units	57,253	—	—	—	—	—
Stock-based compensation	—	—	4,978	—	—	4,978
Net loss	—	—	—	(16,679)	—	(16,679)
Balances at March 31, 2022	35,073,602	35	373,053	(305,381)	—	67,707
Exercise of stock options	55,941	—	322	—	—	322
Issuance of common stock upon release of restricted stock units	13,075	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	50,551	—	1,239	—	—	1,239
Stock-based compensation	—	—	6,161	—	—	6,161
Net loss	—	—	—	(15,398)	—	(15,398)
Unrealized loss on investments, net	—	—	—	—	(2)	(2)
Balances at June 30, 2022	35,193,169	$ 35	$ 380,775	$ (320,779)	$ (2)	$ 60,029

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

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

(in thousands)	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Cash flows from operating activities		
Net loss	$ (29,944)	$ (32,077)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,384	922
Stock-based compensation expense	19,037	11,139
Accretion of discounts on investments, net	(3,362)	(64)
Amortization of debt discount and debt issuance costs	114	91
Amortization of right-of-use asset	552	496
Non-cash interest expense	399	474
Loss on extinguishment of debt	—	245
Loss on disposal of property and equipment	144	175
Change in accounts receivable allowances	19	(3)
Provision for excess and obsolete inventories	14	(3)
Changes in assets and liabilities:		
Accounts receivable	(3,537)	(3,944)
Inventories	213	239
Prepaid expenses and other current assets	(619)	(1,242)
Other assets	(124)	(37)
Accounts payable	2,735	1,076
Accrued liabilities	(2,977)	(2,620)
Other liabilities	(811)	2
Net cash used in operating activities	(16,763)	(25,131)
Cash flows from investing activities		
Purchases of property and equipment	(721)	(3,049)
Purchases of investments	(114,131)	(21,173)
Proceeds from maturity of investments	101,800	—
Net cash used in investing activities	(13,052)	(24,222)
Cash flows from financing activities		
Proceeds from issuance of common stock	2,702	1,729
Proceeds from long-term debt	—	75,000
Principal repayment of debt	—	(49,000)
Payments of debt issuance costs	—	(970)
Net cash provided by financing activities	2,702	26,759
Net change in cash, cash equivalents and restricted cash	(27,113)	(22,594)
Cash, cash equivalents and restricted cash, beginning of period	55,513	110,463
Cash, cash equivalents and restricted cash, end of period	$ 28,400	$ 87,869
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 2,892	$ 1,087
Noncash investing and financing activities:		
Accounts payable and accrued liabilities for purchases of property and equipment	$ 56	$ 105
Right-of-use asset obtained in exchange for lease obligation	$ 2,504	$ 903
Unpaid debt issuance costs	$ —	$ 119

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

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

1. Organization

The Company

Silk Road Medical, Inc., or 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 products enable a 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.

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 condensed balance sheet as of December 31, 2022, and related disclosures, have been derived from the audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements have been prepared on the same basis as the Company’s annual 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 financial information. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other interim period or for any other future year.

The accompanying interim unaudited condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022 included in the Company's annual report on Form 10-K filed with the SEC on February 28, 2023.

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 judgment when making estimates related to provisions for accounts receivable and excess and obsolete inventories, the valuation of deferred tax assets, the reserves for sales returns, and stock-based compensation. 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 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, 2023 and December 31, 2022. The carrying amounts of certain of the Company’s financial instruments, which include 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 debt bears interest at the prevailing market rates for instruments with similar characteristics (Level 2 within the fair value hierarchy); accordingly, the carrying value of this instrument approximates its fair value.

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 recorded at fair value, based on quoted market prices. As of June

Silk Road Medical, Inc.
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(unaudited)

30, 2023 and December 31, 2022, the Company's cash equivalents were entirely comprised of investments in money market funds.

Restricted cash as of December 31, 2022 consisted of a letter of credit of $155,000, representing collateral for the Company's facility lease in California. The Company had no restricted cash as of June 30, 2023.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have original maturities greater than 90 days, but less than one year as of the balance sheet date. Long-term investments have maturities greater than one year as of the balance sheet date. All investments are recorded at fair value based on the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss). Realized gains and losses are included in earnings and are derived based on the specific-identification method for determining the costs of investments sold and were insignificant for the three and six months ended June 30, 2023 and 2022. Amortization of premiums and accretion of discounts are reported as a component of interest income.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the investment. The Company evaluates the securities in an unrealized loss position for expected credit losses by considering factors such as historical experience, market data, issuer-specific factors, current economic conditions and credit ratings. The Company did not recognize any credit losses on its available-for-sale securities during the three and six months ended June 30, 2023 and 2022.

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, investments and accounts receivable to the extent of the amounts recorded on the balance sheet. Cash, cash equivalents, and investments are deposited in financial institutions which, at times, may be in excess of federally insured limits. Cash equivalents are invested in highly rated money market funds. The Company invests in a variety of financial instruments, such as, but not limited to, commercial paper, corporate bonds/notes, U.S. government securities, U.S. treasury bills, agency bonds/notes and, by policy, limits the amount of credit exposure with any one financial institution or commercial issuer. The Company has not experienced any material losses on its deposits of cash and cash equivalents or investments during the three and six months ended June 30, 2023 and 2022.

As of June 30, 2023 and December 31, 2022, a portion of the Company's cash and cash equivalents was maintained with Silicon Valley Bank, a division of First Citizens Bank, or SVB, and exceeded federally insured limits. Substantially all of the Company's cash equivalents and investments reside in a custodial account held by a third party, in which SVB Asset Management is the advisor. On March 10, 2023, SVB was shut down and placed under receivership with the Federal Deposit Insurance Corporation, or FDIC, by the California Department of Financial Protection and Innovation. On March 26, 2023, the FDIC announced it had entered into a purchase and assumption agreement with First Citizens Bank & Trust Company under which all of SVB's deposits were assumed. As of the issuance date of these financial statements, the Company has not experienced any losses on its deposits and all of the Company's cash deposited with SVB has been accessible to the Company.

The Company's accounts receivable are due from a variety of hospitals and medical centers in the United States. As of June 30, 2023 and December 31, 2022, no customer represented 10% or more of the Company's accounts receivable. For the three and six months ended June 30, 2023 and 2022, there were no customers that represented 10% or more of revenue.

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 expected credit losses on customer accounts.

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

Silk Road Medical, Inc.
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Transcarotid Stent System, manufactured by Cordis Corporation, or Cordis. 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 government and 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 U.S. Food and Drug Administration, or 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.

Leases

The Company accounts for its leasing arrangements in accordance with Accounting Standards Codification, or ASC 842, "Leases." The Company considers if an arrangement is a lease at inception if it obtains the right to control the use of an identified asset under a leasing arrangement with an initial term greater than twelve months. The Company determines whether a contract conveys the right to control the use of an identified asset for a period of time if the contract contains both the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the identified asset. The Company also evaluates the nature of each lease 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 considers renewal options in the determination of the lease term if the option to renew is reasonably certain. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease costs, which consists primarily of taxes, insurance and common area maintenance costs, are expensed as incurred. The Company elected to account for contracts that contain lease and non-lease components as a single component, consistent with its historical practice. The Company does not have any finance leases.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "Revenue from Contracts with Customers." 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.

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. 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. 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.

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

As of June 30, 2023 and December 31, 2022, the Company recorded $237,000 and $148,000, respectively, of unbilled receivables, which are included in accounts receivable, net on the condensed balance sheet, as the Company has an unconditional right to payment as of the end of the applicable period.

The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price. Costs associated with product sales, which include commissions and royalties, are expensed 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 goods sold in the condensed 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 and considers other factors that it believes could significantly impact its expected returns, which provisions are classified within accrued liabilities on the condensed balance sheet. 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 California and Minnesota facilities and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, manufacturing overhead costs, direct labor, scrap, product rework, 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 control, 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. The Company entered into the lease for its additional facility in Minnesota in May 2021 and did not begin commercial production of the ENROUTE Neuroprotection System until the third quarter of 2022. During this time, the Company experienced additional overhead expenses related to its investment in the start-up phase of its manufacturing capacity expansion, which were recorded as a period expense.

Stock–Based Compensation

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board, or 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, restricted stock units, performance stock units, and shares issued under its employee stock purchase plan. 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. The Company accounts for option forfeitures as they occur.

The Company accounts for stock-based compensation for restricted stock units at their fair value, based on the closing market price of the Company’s common stock on the date of grant. These costs are recognized on a straight-line basis over the requisite service period, which is usually the vesting period.

The Company accounts for stock-based compensation for performance stock units with market-based conditions at their fair value on the date of the award using the Monte Carlo simulation model. These costs are recognized over the requisite service period, which is usually the vesting period, regardless of the likelihood of achievement of the market-based performance criteria.

The Company accounts for stock-based compensation for its employee stock purchase plan based on the estimated fair value of the options on the date of grant. The Company estimates the grant date fair value using an option pricing model for each purchase period. These costs are recognized on a straight-line basis over the offering period.

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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 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 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.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on investments classified as available-for-sale. For the three and six months ended June 30, 2023 and 2022, the Company’s unrealized gains and losses on available-for-sale investments represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the condensed statements of operations and comprehensive loss. Accumulated other comprehensive income (loss) is presented in the accompanying condensed balance sheets as a component of stockholders' equity.

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, common stock options, restricted stock units and performance stock units 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.

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,	
	2023	2022	2023	2022
Net loss	$ (13,484)	$ (15,398)	$ (29,944)	$ (32,077)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	38,765,166	35,143,178	38,649,327	35,083,569
Net loss per share, basic and diluted	$ (0.35)	$ (0.44)	$ (0.77)	$ (0.91)

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:

	June 30,	
	2023	2022
Common stock options	3,668,825	4,175,300
Restricted stock units and performance stock units	1,749,463	1,112,936
	5,418,288	5,288,236

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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. Primarily 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, 2023 and 2022, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

The Company has considered all recent accounting pronouncements that have not yet been adopted and believe there are none that could potentially have a material impact on the Company’s financial statements and related disclosures.

4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and investments. 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 are identical assets and liabilities;
- Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities;
- Level 3 – unobservable inputs.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company’s investments are classified within Level 1 of the fair value hierarchy include money market funds valued using quoted market prices and U.S. treasury bills valued using broker or dealer quotations with reasonable levels of price transparency. Investments classified within Level 2 include commercial paper, which are valued using model-based valuation techniques, and corporate bonds/notes, U.S. government securities and agency bonds/notes, which are valued based upon quoted market prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets.

The following tables set forth by level within the fair value hierarchy the Company’s assets that are reported at fair value as of June 30, 2023 and December 31, 2022, using the inputs defined above (in thousands):

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 28,162	$ —	$ —	$ 28,162
Commercial paper	—	35,674	—	35,674
Corporate bonds/notes	—	31,008	—	31,008
U.S. government securities	—	40,673	—	40,673
Agency bonds/notes	—	66,490	—	66,490
	$ 28,162	$ 173,845	$ —	$ 202,007

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Notes to Condensed Financial Statements
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	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 55,158	$ —	$ —	$ 55,158
U.S. treasury bills	19,776	—	—	19,776
Commercial paper	—	48,875	—	48,875
Corporate bonds/notes	—	1,515	—	1,515
U.S. government securities	—	83,270	—	83,270
Asset-backed securities	—	1,996	—	1,996
Agency notes	—	2,884	—	2,884
	$ 74,934	$ 138,540	$ —	$ 213,474

There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2023 and 2022.

5. Balance Sheet Components

Investments

The fair value of the Company's cash equivalents and available-for-sale investments as of June 30, 2023 and December 31, 2022 are as follows (in thousands):

	June 30, 2023			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 28,162	$ —	$ —	$ 28,162
Commercial paper	35,674	—	—	35,674
Corporate bonds/notes	31,102	—	(94)	31,008
U.S. government securities	40,709	—	(36)	40,673
Agency bonds/notes	66,691	4	(205)	66,490
	$ 202,338	$ 4	$ (335)	$ 202,007
Classified as:				
Cash equivalents				$ 28,162
Short-term investments				159,961
Long-term investments				13,884
				$ 202,007

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	December 31, 2022			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Estimated Fair Value
Money market funds	$ 55,158	$ —	$ —	$ 55,158
U.S. treasury bills	19,772	4	—	19,776
Commercial paper	48,875	—	—	48,875
Corporate bonds/notes	1,528	—	(13)	1,515
U.S. government securities	83,432	2	(164)	83,270
Asset-backed securities	2,000	—	(4)	1,996
Agency notes	2,876	8	—	2,884
	$ 213,641	$ 14	$ (181)	$ 213,474
Classified as:				
Cash equivalents				$ 55,158
Short-term investments				158,316
				$ 213,474

The following table summarizes the fair value of the Company’s cash equivalents, and available-for-sale investments classified by maturity as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Amounts maturing within one year	$ 188,123	$ 213,474
Amounts maturing after one year through two years	13,884	—
	$ 202,007	$ 213,474

Available-for-sale investments held as of June 30, 2023 had a weighted average days to maturity of 222 days.

The following table presents the Company’s available-for-sale investments that were in an unrealized loss position as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023		December 31, 2022	
	Less than 12 months		Less than 12 months	
Assets:	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds/notes	$ 30,727	$ (94)	$ 1,490	$ (13)
U.S. government securities	30,669	(36)	73,329	(164)
Asset-backed securities	—	—	1,994	(4)
Agency bonds/notes	60,411	(205)	—	—
	$ 121,807	$ (335)	$ 76,813	$ (181)

Inventories

Components of inventories were as follows (in thousands):

	June 30, 2023	December 31, 2022
Raw materials	$ 5,937	$ 4,913
Finished products	13,130	14,380
	$ 19,067	$ 19,293

As of June 30, 2023 and December 31, 2022, there were no work-in-process inventories.

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Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued payroll and related expenses	$ 12,200	$ 15,216
Operating lease liability	1,669	1,844
Accrued royalty expense	1,050	973
Accrued professional services	606	781
Accrued travel expenses	847	775
Provision for sales returns	573	540
Accrued interest payable	501	519
Deferred revenue	220	253
Accrued clinical expenses	251	249
Accrued other expenses	842	815
Total	$ 18,759	$ 21,965

6. Long-term Debt

In May 2022, the Company entered into a Loan and Security Agreement, or Loan Agreement, with Oxford Finance LLC and its agents, or Oxford Finance, which provides for a $225,000,000 loan facility, comprised of a $25,000,000 secured revolving credit facility and a $200,000,000 secured term loan facility. The term loans are available in three tranches. The first $75,000,000 tranche of term loans was available at closing in May 2022. A second tranche of $75,000,000 of term loans is available through December 31, 2024. A third tranche of $50,000,000 would be available through December 31, 2024 so long as, at the time of draw, the Company has consolidated trailing 12-month revenues equal to at least 90% of the sum of the outstanding term loans plus the amount of any requested third tranche term loans.

Upon request of the Company, the revolving credit facility will be increased from $25,000,000 to $50,000,000. The revolving loans are available subject to a borrowing base equal to 85% of eligible receivables plus 50% of eligible inventory, up to the lesser of 40% of the borrowing base or $10,000,000, in the case of eligible inventory. The revolving facility will be available to the Company upon completion of an initial collateral audit.

The revolving loans and the term loans mature on May 1, 2027. The principal amount of outstanding revolving loans, together with accrued and unpaid interest, is due on the maturity date. The term loans begin to amortize in equal monthly installments beginning on July 1, 2026. As the Company achieved a specified consolidated trailing twelve-month revenue target, it has the option to extend the first amortization date for the term loans to July 1, 2027. Such election may be made no earlier than June 30, 2023 and no later than thirty (30) days prior to July 1, 2026. If the Company exercises this option, then the maturity date for both the revolving loans and the term loans will be May 1, 2028.

The revolving loans accrue interest at the greater of 1-month Secured Overnight Financing Rate (SOFR), or the Index Rate, and 0.85%, plus a margin of 3.00%. The term loans accrue interest at the greater of the Index Rate and 0.85%, plus a margin of 5.00%. The Index Rate is capped at 2.50% for purposes of the Loan Agreement. Interest on both revolving loans and term loans is payable monthly in arrears. The Company may borrow, prepay and reborrow revolving loans, without premium or penalty. The term loans once repaid or prepaid may not be reborrowed. Term loans may be prepaid in full, or in part in increments of $10,000,000. The Company is required to pay a prepayment fee of 3.0% for prepayments of term loans made in the first year after closing, 2.0% for prepayments of term loans made in the second year after closing, 1.0% for prepayments of term loans made in the third year after closing and no prepayment fees thereafter. Upon the earlier of prepayment or maturity of the term loans, the Company is required to pay a fee of 5.0% of the aggregate original principal amount of the funded term loans, which fee increases to 6.75% if the Company exercises its option to extend the amortization date and maturity date. The Company is also obligated to pay other customary fees for a loan facility of this size and type.

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Also in May 2022, the Company borrowed the first $75,000,000 tranche of the term loan and used a portion of the proceeds to pay off and terminate the prior term loan agreement with Stifel Bank totaling $49,181,000, which included a final interest payment of $181,000. The Company recognized a loss on debt extinguishment of $245,000 in connection with the early termination of its prior term loan agreement with Stifel Bank. The Success Fee Agreement obligation, of $367,500, survives the Stifel Bank debt repayment and terminates on October 29, 2025.

Obligations under the Loan Agreement are secured by substantially all of the Company's assets. The Loan Agreement requires the Company to maintain consolidated trailing twelve-month revenues of at least 75% of the outstanding principal amount of the term loans, measured as of the last day of each fiscal quarter; or if the revenue target is not achieved, the Company must have maintained unrestricted cash and cash equivalents (net of outstanding revolving loans) subject to control agreements in favor of Oxford Finance equal to at least 50% of the outstanding principal amount of the term loans. Additionally, the Loan Agreement contains customary affirmative and negative covenants, including covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

The events of default under the Loan Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of the Company's obligations under the Loan Agreement, the termination of the lender's commitments, a 5% increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement.

As of June 30, 2023, the aggregate outstanding principal balance under the term loan facility was $75,000,000 with the variable interest rate capped at the maximum rate of 7.50%, and no amounts were outstanding under the revolving credit facility of the Loan Agreement. As of June 30, 2023, the Company was in compliance with all applicable financial covenants.

Future payments under the Oxford Finance term loan agreement as of June 30, 2023 are as follows (in thousands):

Year Ending December 31:	**Amount**
2023	$ 2,875
2024	5,719
2025	5,703
2026	45,699
2027	34,517
	94,513
Add: Accretion of closing fees	925
	95,438
Less: Amount representing interest	(19,513)
Less: Amount representing debt discount and debt issuance costs	(821)
Present value of minimum payments	$ 75,104

7. Commitments and Contingencies

Operating Lease and Rights-of-Use

The Company's operating lease obligation at its corporate headquarters in California consists of leased office, laboratory, and manufacturing space under a non-cancellable operating lease that expires in October 2027. In May 2023, the Company extended the lease term for an additional three years and recorded an additional $2,504,000 right-of-use asset and lease liability from the remeasurement. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of five years.

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The Company’s non-cancelable operating lease obligation at its facilities in Minnesota consists of additional office, laboratory and manufacturing space and expires in November 2029. The lease agreement includes a renewal provision allowing the Company to extend this lease for two additional five year terms.

Operating lease costs were $431,000 and $379,000 for the three months ended June 30, 2023 and 2022, respectively, and $838,000 and $744,000 for the six months ended June 30, 2023 and 2022, respectively. Cash paid (net of tenant improvement allowances received) for amounts included in the measurement of operating lease liabilities was $330,000 and $146,000 for the three months ended June 30, 2023 and 2022, respectively, and $689,000 and $(558,000) for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the weighted average discount rate was approximately 7.25% and the weighted average remaining lease term was 5.56 years. As of June 30, 2022, the weighted average discount rate was approximately 6.56% and the weighted average remaining lease term was 5.98 years. Balance sheet information as of June 30, 2023 and December 31, 2022 consists of the following (in thousands):

Operating Lease:	**June 30, 2023**	**December 31, 2022**
Operating lease right-of-use assets in other non-current assets	$ 7,034	$ 5,081
Operating lease liabilities in accrued liabilities	$ 1,669	$ 1,844
Operating lease liabilities in other liabilities	7,989	5,998
Total operating lease liabilities	$ 9,658	$ 7,842

The following table summarizes the Company’s operating lease payments as of June 30, 2023 (in thousands):

Year Ending December 31:	**Amount**
2023	$ 991
2024	1,991
2025	2,130
2026	2,255
2027 and thereafter	4,459
Total lease payments	$ 11,826
Less: imputed interest	(2,168)
Present value of lease liabilities	$ 9,658

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. As of June 30, 2023, the Company had non-cancellable purchase obligations to suppliers of $22,566,000. In addition, the Company has minimum purchase commitments under its amended supply agreement with Cordis from July 2024 through February 2029 which require a specified minimum volume commitment based on the actual units purchased during the prior year period from July 1 through June 30, with the unit purchase price dependent upon annual volume during the same prior year period.

Indemnification

In the normal course of business, the Company enters into contracts and agreements with suppliers and other parties 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 or officer 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 or officer may be subject to any proceeding arising out of acts or omissions of such director or officer in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. 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, 2023.

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 rights 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 as of June 30, 2023 and December 31, 2022.

8. Stock-Based Compensation Plans

As of June 30, 2023, the Company has reserved 7,951,555 shares of common stock for issuance under the 2019 Equity Incentive Plan, or the 2019 Plan.

A summary of the shares available for issuance under the 2019 Plan is as follows:

	Number of Shares
Balances, December 31, 2022	2,209,072
Authorized	1,534,238
Allowance for Performance Stock Units for overperformance	(99,350)
Granted/Awarded	(700,745)
Cancelled	47,787
Balances, June 30, 2023	2,991,002

The exercise price of Incentive Stock Options, or ISOs, and Non-Statutory Stock Options, or NSOs, shall not be less than 100% and 85%, respectively, of the estimated fair value of the shares on the date of grant 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 ten years and generally vest over four years from the date of grant.

Stock option activity under the Company's 2007 Stock Option Plan, 2015 Equity Incentive Plan and 2019 Plan is set forth below:

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances, December 31, 2022	3,839,858	$ 24.22	6.41	$ 112,755
Options granted	19,898	33.57		
Options exercised	(176,957)	7.58		
Options cancelled	(13,974)	53.72		
Balances, June 30, 2023	3,668,825	$ 24.96	6.02	$ 44,529
Vested and exercisable at June 30, 2023	2,998,381	$ 21.13	5.54	$ 44,393
Vested and expected to vest at June 30, 2023	3,668,825	$ 24.96	6.02	$ 44,529

The aggregate intrinsic value of options exercised during the six months ended June 30, 2023 was $7,514,000. 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.

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Restricted Stock Units

Restricted stock units, or RSUs, are granted under the 2019 Plan and generally vest over four years in annual equal increments. A summary of RSU activity for the six months ended June 30, 2023 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Balances, December 31, 2022	1,122,356	$ 42.70
Awards granted	581,497	44.61
Awards vested	(33,813)	43.30
Awards canceled	(227,395)	40.18
Balances, June 30, 2023	1,442,645	$ 43.86
Expected to vest at June 30, 2023	1,442,645	$ 43.86

Performance Stock Units

Performance stock units, or PSUs, are granted under the 2019 Plan and generally vest over three years. A summary of PSU activity for the six months ended June 30, 2023 is as follows:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Balances, December 31, 2022	207,468	$ 77.12
Awards granted	99,350	69.40
Awards vested	—	—
Awards canceled	—	—
Balances, June 30, 2023	306,818	$ 74.62
Expected to vest at June 30, 2023	306,818	$ 74.62

The number of shares expected to vest as of June 30, 2023 reflects the performance and vesting of PSUs at 100% of the target value of shares granted.

2019 Employee Stock Purchase Plan

As of June 30, 2023, 318,126 shares of common stock have been issued to employees participating in the 2019 Employee Stock Purchase Plan, or the ESPP, and 1,504,289 shares were available for future issuance under the ESPP.

Stock-Based Compensation

In March 2023, the Company awarded an aggregate of 99,350 PSUs, assuming target performance. Up to one-third of the target award can be earned and vested at the end of the first and second annual measurement periods based on the total stockholder return, or TSR, of the Company's common stock price relative to a group of peer companies, and up to 200% of the target award at the end of the three year performance measurement period. The fair value of the PSUs was estimated using the Monte Carlo simulation model and the following assumptions: peer companies volatility of 62.3%, Company volatility of 61.2%, risk-free interest rate of 4.58%, correlation with index of 0.38, and dividend yield of 0%.

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The following table summarizes the total stock-based compensation expense included in the condensed statements of operations and comprehensive loss for all periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of goods sold	$ 444	$ 278	$ 834	$ 499
Research and development expenses	1,943	1,302	3,576	2,371
Selling, general and administrative expenses	7,811	4,581	14,627	8,269
	$ 10,198	$ 6,161	$ 19,037	$ 11,139

As of June 30, 2023, there was total unrecognized compensation costs of $12,325,000 related to stock options expected to be recognized over a period of approximately 2.04 years, a total of $71,292,000 of unrecognized compensation costs related to unvested RSUs and PSUs expected to be recognized over a period of approximately 2.81 years and $402,000 of unrecognized compensation costs related to the ESPP, which the Company will recognize over 0.39 years.

9. 401(k) Plan

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code, or the IRC, under which participants may contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary matching contribution to the 401(k) plan and may make a discretionary employer contribution to each eligible employee each year. Effective January 2022, the Company matched employees' contributions to the 401(k) plan at 50% of the first 6% of compensation deferred to the 401(k) plan. The Company's matching contributions were $533,000 and $454,000 for the three months ended June 30, 2023 and 2022, respectively, and $1,216,000 and $1,043,000 for the six months ended June 30, 2023 and 2022, respectively.

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 our unaudited interim condensed financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2022. 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” and the “Cautionary Note Regarding Forward-Looking Statements” beginning on page 2.

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 relatively 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. In the second quarter of 2022, we announced FDA label and Medicare coverage expansions for the use of TCAR in standard surgical risk patients. TCAR is reimbursed based on established CPT codes and ICD-10 codes related to carotid stenting that track to MS-DRG classifications. We recently expanded our product portfolio with the limited market release of our ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter in the fourth quarter of 2022 and a full market release during the second quarter of 2023. We now have a product portfolio consisting of five single-use components. During the six months ended June 30, 2023, more than 12,200 TCAR procedures were performed in the United States using our products.

Also in the second quarter of 2023, we received 510(K) clearance for our next generation neuroprotection system, or ENROUTE NPS Plus, which supports additional ease-of-use and further minimizes the risk for complications. A limited market release is planned for late 2023. In addition, we received PMA approval for tapered configurations of our ENROUTE Stent in mid-June, which will provide greater choice for physicians to address the diversity of patient specific anatomy. We anticipate launching our tapered ENROUTE stents in the first half of 2024.

Products for carotid artery stenting, or CAS, including our TCAR products, are covered for Medicare beneficiaries under certain circumstances under the Centers for Medicare and Medicaid Services, or CMS’s, National Coverage Decision, or NCD, 20.7 for Percutaneous Transluminal Angioplasty. In January 2023, the CMS initiated a national coverage analysis of NCD 20.7. The proposed decision memo was released on July 11, 2023 with a public comment period ending on August 10, 2023. In the proposed decision memo, CMS proposes that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a FDA approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries in patients with symptomatic carotid artery stenosis ≥50% and in patients with asymptomatic carotid artery stenosis ≥70%; provided, that: (1) independent neurological assessment before and after CAS, must be performed to assess procedural risks; (2) evaluation of the extent and severity of carotid artery stenosis must use one of the following non-invasive modalities for first-line imaging: duplex ultrasound, computed tomography angiography, or magnetic resonance angiography; and (3) prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary, which shared decision-making interaction must involve the use of a validated shared decision-making tool and include: (i) discussion of all treatment options for carotid stenosis to ensure the beneficiary is familiar with and aware of all treatment options including, but not limited to, procedures that fall within the parameters of this NCD; (ii) explanation of risks and benefits for each option specific to the beneficiary’s clinical condition; (iii) integration of clinical guidelines (e.g., patient life-expectancy); and (iv) discussion and incorporation of beneficiary’s personal preferences and priorities in choosing a treatment plan. The national coverage analysis completion date is expected on October 9, 2023. We believe that if the final NCD is consistent with the proposed decision memo, there could be rising interest and awareness in minimally-invasive carotid stenting procedures including TCAR, driven by CMS’s stated goals for broader patient access, which in turn is driven by the proposed addition of shared decision-making with patients and the proposed removal of facility and registry requirements for providers.

While we do not currently sell our products in markets outside the United States, we are pursuing regulatory clearances in Japan and China. In Japan, we received Shonin approval for the ENROUTE NPS and the ENROUTE stent in the fourth quarter of 2022 and are actively investigating potential distribution partners while we work towards a reimbursement submission later this year. In addition, in the first quarter of 2023, we received approval from China's National Medical Products Administration for our ENROUTE NPS and we are now focused on approval for our ENROUTE stent. In both geographies, we are conducting regulatory activities to support future clearance of our next-generation ENROUTE NPS Plus that was cleared in the U.S in the second quarter of 2023.

We designed our U.S. 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 carotid endarterectomy, or CEA, and transfemoral carotid artery stenting, 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. Our sales and marketing efforts are focused on leveraging our broad commercial footprint to drive utilization across our trained physician base. This includes onboarding and training new sales, sales management, and other field professionals to expand and align our territories and increase touch points with our customers. We also have recently increased our marketing efforts on focusing on reaching potential patients and educating them on the benefits of TCAR.

We manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, and at our Plymouth, Minnesota facility beginning in the third quarter of 2022. In May 2023, we entered into an amendment to our lease agreement covering our corporate headquarters in Sunnyvale, California to extend the terms of our lease for an additional three years to October 2027, subject to an existing option to further extend the term for an additional five years. We believe our combined facilities will be sufficient to meet our manufacturing needs for at least the next five years. We use 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. Our ENROUTE Enflate product is manufactured under an agreement with Nordson Medical Ireland, Ltd. Many of our third party manufacturers and outside vendors are currently single-source suppliers. We have increasingly become concerned with the ability of a critical supplier of certain polymer tubing materials, and related components used in our products to provide our third party manufacturer these polymer tubing materials on a timely basis. If this supplier is unable to provide these polymer tubing materials on a timely basis, it could result in TCAR product delays to our customers, which, in turn, would adversely affect our results of operations.

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. Each of our products is purchased individually, and the majority of our revenue is derived from sales of the ENROUTE NPS and the ENROUTE stent. No single customer accounted for 10% or more of our revenue during the three and six months ended June 30, 2023 and 2022. Key performance indicators that drive revenue include the number of active sales territories, the number of trained physicians certified to perform TCAR, the number of hospital accounts that perform our procedures, the number of procedures per physician or hospital account, revenue per procedure, introduction of new products, product mix and average selling prices for our products. We expect our revenue to continue to increase in the future through increased adoption of TCAR and as a result of the introduction of new products and international expansion. Any decreases in our key performance indicators could have a negative impact on our future revenue. In addition, we have expanded our sales and marketing infrastructure, including number of sales personnel and sales territories, to help us drive and support revenue growth and we intend to continue this expansion. However, we may continue to experience headwinds due to price pressures, increased labor costs, labor and staffing shortages, hospital capacity and patient behavior caused by COVID-19 or as a result of general macroeconomic factors.

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. Holiday and summer vacations by healthcare providers and/or patients can also affect procedure volumes that in turn affect hospital ordering patterns. We have also seen procedure volumes moderate during major medical conferences when significant portions of our customer base are attending the conferences.

Cost of Goods Sold and Gross Margin

We currently manufacture the ENROUTE NPS at our facilities in California and Minnesota. 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, scrap, product rework, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include the cost of quality control, 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, including primarily average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, replacement of expired product, 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, potentially offset by inflationary pressures and investments in additional operational infrastructure in both our California and Minnesota facilities. Specifically, we are experiencing inflationary and price pressures and increased labor costs and labor and staffing shortages affecting the cost of the components for our TCAR products and the wages that we pay our employees, as well as the wages our vendors pay their employees, due to challenging labor market conditions. We began commercial production at our Plymouth, Minnesota facility during the third quarter of 2022; with two manufacturing facilities, we expect our gross margin to be slightly lower than prior periods in the short term. 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 will reduce costs and have a positive long-term impact on our gross margin. However, our gross margin could fluctuate from quarter to quarter as we introduce new products, execute certain manufacturing engineering projects, adopt new manufacturing processes and technologies, and expand our distribution operations and infrastructure to support our planned long-term growth and risk mitigation. In addition, possible resurgences of COVID-19 and new virus variants may continue to negatively impact our gross margin in the near term due to unfavorable production variances as a result of lower production and lower demand.

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, in each case related to R&D programs. 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. In addition, possible resurgences of COVID-19 and new virus variants may continue to impact our product development efforts and clinical and regulatory matters for the foreseeable future. COVID-19 has and continues to impact enrollment in clinical trials across the medical device industry and may affect any new trials we decide to pursue.

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, reimbursement, 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 anticipated growth in revenue and as we expand our presence. In addition, we plan to continue exploring sales and marketing expansion opportunities in international geographies. While we expect SG&A expenses to increase, we expect SG&A expenses as a percentage of revenue to decrease over time due to anticipated increased revenue.

New virus variants and varying infection rates of COVID-19 may modulate our SG&A expenses over the short term. The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion may also delay preparation for and launch of such expansion efforts.

Interest Income (Expense), net

Interest income (expense), net consists primarily of cash interest expense incurred on our outstanding indebtedness and non-cash interest expense related to the accretion of closing fees and amortization of debt discount and issuance costs associated with our debt agreements. Our interest expense was offset by interest income earned on our cash, cash equivalents and investments.

Results of Operations:

(in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Revenue	$ 45,298	$ 33,173	$ 85,429	$ 61,193
Costs of goods sold	13,004	9,012	25,530	17,588
Gross profit	32,294	24,161	59,899	43,605
Operating expenses:				
Research and development	10,780	10,655	21,213	18,778
Selling, general and administrative	35,830	27,700	69,913	54,975
Total operating expenses	46,610	38,355	91,126	73,753
Loss from operations	(14,316)	(14,194)	(31,227)	(30,148)
Interest income (expense), net	722	(909)	1,316	(1,518)
Loss on debt extinguishment	—	(245)	—	(245)
Other income (expense), net	110	(50)	(33)	(166)
Net loss	$ (13,484)	$ (15,398)	$ (29,944)	$ (32,077)

Comparison of Three Months Ended June 30, 2023 and 2022

Revenue. Revenue increased $12.1 million, or 37%, to $45.3 million during the three months ended June 30, 2023, compared to the three months ended June 30, 2022. The increase in revenue was attributable to an increase in the number of products sold as physicians performed more TCAR procedures and as we expanded our sales territories, increased the number of new accounts, and trained more physicians in TCAR.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $4.0 million, or 44%, to $13.0 million during the three months ended June 30, 2023, compared to the three months ended June 30, 2022. This increase was primarily attributable to the increase in the number of products sold. Gross margin for the three months ended June 30, 2023 decreased to 71%, compared to 73% in the three months ended June 30, 2022. Gross margin in the current year period was impacted by higher manufacturing costs associated with labor and materials and having two manufacturing facilities compared to one facility in the prior year.

Research and Development Expenses. R&D expenses increased $0.1 million, or 1%, to $10.8 million during the three months ended June 30, 2023, compared to $10.7 million during the three months ended June 30, 2022. The increase in R&D expenses was driven primarily by growth in personnel, including specifically, an increase of $1.1 million in personnel-related expenses, including stock-based compensation, as a result of increased headcount. The increase in personnel-related expenses was partially offset by decreases in outside services fees and product development materials and costs.

Selling, General and Administrative Expenses. SG&A expenses increased $8.1 million, or 29%, to $35.8 million during the three months ended June 30, 2023, compared to $27.7 million during the three months ended June 30, 2022. This increase was due primarily to the continued expansion of our sales team and commercial efforts during the current year period, including specifically, an increase of $7.2 million in payroll and personnel-related expenses, an increase of $0.3 million in consulting and professional fees, an increase of $0.3 million related to the allocated costs of facilities and other related expenses, particularly related to our new facility in Minnesota and increases in our marketing and tradeshow expenses. Personnel-related expenses included stock-based compensation expense of $7.8 million and $4.6 million for the three months ended June 30, 2023 and 2022, respectively.

Interest Income (Expense), Net. Interest income (expense), net increased $1.6 million, or 180%, to income of $0.7 million during the three months ended June 30, 2023, compared to an expense of $0.9 million during the three months ended June 30, 2022. This increase in net interest income was attributable to higher balances and higher weighted average interest rates on our cash, cash equivalents and investments, partially offset by both the increased interest rate and increased amount of borrowings outstanding under our loan agreement, as a result of our May 2022 refinancing of our debt obligation, as compared with the prior period.

Other Income (Expense), Net. Other income (expense), net was income of $0.1 million during the three months ended June 30, 2023 compared to an expense of $0.1 million during the three months ended June 30, 2022. This increase in net other income was primarily attributable to $0.1 million received under a job creation fund.

Comparison of Six Months Ended June 30, 2023 and 2022

Revenue. Revenue increased $24.2 million, or 40%, to $85.4 million during the six months ended June 30, 2023, compared to the six months ended June 30, 2022. The increase in revenue was attributable to an increase in the number of products sold as physicians performed more TCAR procedures and as we expanded our sales territories, increased the number of new accounts, and trained more physicians in TCAR. Although revenue increased during the six months ended June 30, 2023, as compared with the prior year period, the COVID-19 pandemic negatively impacted revenue early in the first quarter of 2022, as resurgences due to the Omicron variant adversely effected hospital capacity and patient behaviors.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $7.9 million, or 45%, to $25.5 million during the six months ended June 30, 2023, compared to the six months ended June 30, 2022. This increase was primarily attributable to the increase in the number of products sold. Gross margin for the six months ended June 30, 2023 decreased to 70%, compared to 71% in the six months ended June 30, 2022. The gross margin decrease in the current year period was driven by unfavorable production variances, as a result of production rework being completed in the first quarter of 2023, and also by higher manufacturing costs associated with labor and materials and having two manufacturing facilities compared to one facility in the prior year. Gross margin for the prior year period was adversely affected by COVID-19 related production issues in the first quarter.

Research and Development Expenses. R&D expenses increased $2.4 million, or 13%, to $21.2 million during the six months ended June 30, 2023, compared to $18.8 million during the six months ended June 30, 2022. The increase in R&D expenses was driven by growth in personnel and investment in new and ongoing R&D programs. The increase in R&D expenses was primarily attributable to an increase of $2.2 million in personnel-related expenses, including stock-based compensation, as a result of increased headcount, an increase of $0.6 million related to product development materials, and an increase of $0.5 million in clinical and regulatory expenses, partially offset by a decrease in outside services fees.

Selling, General and Administrative Expenses. SG&A expenses increased $14.9 million, or 27%, to $69.9 million during the six months ended June 30, 2023, compared to $55.0 million during the six months ended June 30, 2022. The increase in SG&A costs was due to the continued expansion of our sales team and commercial efforts, compared to the prior year period. The increase in SG&A expenses is primarily attributable to an increase of $13.1 million in payroll and personnel-related expenses, an increase of $0.6 million in consulting and professional fees, an increase of $0.5 million in the allocated costs of facilities and other related expenses, an increase of $0.4 million in physician training and travel-related costs, and an increase of $0.3 million in software-related costs. Personnel-related expenses included stock-based compensation expense of $14.6 million and $8.3 million for the six months ended June 30, 2023 and 2022, respectively.

Interest Income (Expense), Net. Interest income (expense), net increased $2.8 million, or 187%, to income of $1.3 million during the six months ended June 30, 2023, compared to an expense of $1.5 million during the six months ended June 30, 2022. The increase in net interest income is attributable to higher average balances and weighted average interest rates on our cash, cash equivalents and investments, partially offset by both the increased interest rate and increased amount of borrowings outstanding under our loan agreement as a result of our May 2022 refinancing of our debt obligation as compared with the prior period.

Other Income (Expense), Net. Other income (expense), net was an expense of $33,000 for the six months ended June 30, 2023, compared to an expense of $0.2 million during the six months ended June 30, 2022. Net other expense in both periods were attributable to losses on the disposal of property and equipment. The current period expense was offset by $0.1 million received under a job creation fund.

Liquidity and Capital Resources

Sources of Liquidity

To date, our principal sources of liquidity have been net proceeds from sales of our common stock in public offerings, private sales of our equity securities and debt financings, as well as revenue from product sales, which we expect to be our primary source of future liquidity, and to a lesser extent, proceeds from stock option exercises and employee stock purchase plan purchases. As of June 30, 2023, we had cash, cash equivalents and investments of $202.2 million, $75.0 million outstanding principal in term loans, an additional $125.0 million in available but unused term loans and $25.0 million in availability under a revolving credit facility with Oxford Finance LLC and its agent, or Oxford Finance.

On May 27, 2022, we entered into a Loan and Security Agreement, or Loan Agreement, with Oxford Finance, which provides for a $225.0 million loan facility, comprised of a $25.0 million secured revolving credit facility and a $200.0 million secured term loan facility. We concurrently drew down $75.0 million under the term loan facility and used a portion of the proceeds to pay off outstanding amounts under and terminate our prior loan agreement with Stifel Bank. The term loans are available in three tranches. Upon our request, the revolving credit facility will be increased from $25.0 million to $50.0 million. The revolving loans are available subject to a borrowing base equal to 85% of eligible receivables plus 50% of eligible inventory, up to the lesser of 40% of the borrowing base or $10.0 million in the case of eligible inventory. The revolving loans and the term loans mature on May 1, 2027. The principal amount of outstanding revolving loans, together with accrued and unpaid interest, is due on the maturity date. The principal amount of outstanding term loans are required to be repaid in equal monthly installments beginning on July 1, 2026. Since we achieved a specified consolidated trailing twelve-month revenue target, we have an option to extend the first amortization date for the term loans to July 1, 2027, which option must be exercised no earlier than June 30, 2023 and no later than 30 days prior to July 1, 2026. If we exercise this option, then the maturity date for both the revolving loans and the term loans will be May 1, 2028.

Any revolving loans under the Loan Agreement accrue interest at the greater of 1-month Secured Overnight Financing Rate, or SOFR, or the Index Rate, and 0.85%, plus a margin of 3.00%. The term loans accrue interest at the greater of the Index Rate and 0.85%, plus a margin of 5.00%. The Index Rate is capped at 2.50% for purposes of the Loan Agreement. Interest on both revolving loans and term loans is payable monthly in arrears. As of June 30, 2023, the aggregate outstanding principal balance under the term loan facility was $75,000,000 with the variable interest rate capped at the maximum rate of 7.50%, and no amounts were outstanding under the revolving credit facility of the Loan Agreement. As of June 30, 2023, the Company was in compliance with all applicable financial covenants under the Loan Agreement.

In October 2022, we completed an underwritten public offering of approximately 2.7 million shares of our common stock at a public offering price of $43.00 per share, resulting in net proceeds of approximately $109.0 million.

We expect to continue to devote a substantial amount of our capital resources to expand commercialization efforts and increase adoption of TCAR using our products, conduct clinical studies and expand our clinical evidence base, and develop additional products. We also plan to continue exploring sales and marketing expansion opportunities in select international geographies. In addition, as a public company, we incur significant legal, accounting, director and officer liability insurance, exchange listing and SEC compliance, investor relations and other expenses, all of which continue to increase. Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future.

We believe our existing cash, cash equivalents and investments, together with our expected revenue, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months from the issuance date of these financial statements.

Cash Flows

The following table summarizes our cash flows for each of the periods presented below:

	Six Months Ended June 30,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (16,763)	$ (25,131)
Investing activities	(13,052)	(24,222)
Financing activities	2,702	26,759
Net decrease in cash, cash equivalents and restricted cash	$ (27,113)	$ (22,594)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was $16.8 million, consisting of a net loss of $29.9 million and non-cash charges of $18.2 million, partially offset by a net change in net operating assets of $5.1 million. The change in net operating assets was primarily due to increases in accounts receivable, prepaid expenses and other current assets, an increase in accounts payable due to timing of payments and decreases in inventories and also in accrued and other liabilities due to timing of payments. The non-cash charges primarily consisted of stock-based compensation, as well as depreciation and amortization, amortization of right-of-use assets, non-cash interest expense, and a loss on the disposal of property and equipment, partially offset by the accretion of discounts on investments.

Net cash used in operating activities for the six months ended June 30, 2022 was $25.1 million, consisting of a net loss of $32.1 million and non-cash charges of $13.5 million, partially offset by a net change in net operating assets of $6.5 million. The change in net operating assets was primarily due to increases in accounts receivable which increased due to higher revenue, an increase in prepaid expenses and other current assets primarily due to timing of insurance premium payments, an increase in accounts payable due to timing of payments, and decreases in inventories and in accrued liabilities due to timing of payments. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, amortization of right-of-use assets, non-cash interest expense, partially offset by the accretion of discounts on investments, loss on debt extinguishment and a loss on the disposal of property and equipment.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2023 was $13.1 million, consisting of purchases of investments of $114.0 million and purchases of property and equipment of $0.7 million, partially offset by maturities of investments of $101.8 million.

Net cash used in investing activities for the six months ended June 30, 2022 was $24.2 million, consisting of purchases of property and equipment of $3.0 million and purchases of investments of $21.2 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 was $2.7 million consisting of proceeds from stock option exercises and purchases under our employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2022 was $26.8 million consisting of proceeds from the issuance of debt of $74.0 million, net of issuance costs paid and proceeds of $1.7 million from stock option exercises and purchases under our employee stock purchase plan, partially offset by repayment of debt of $49.0 million.

Contractual Obligations and Commitments

On May 3, 2023, we entered into an amendment to our lease agreement covering our corporate headquarters in Sunnyvale, California pursuant to which the term was extended for an additional three years to October 12, 2027, subject to an existing option to further extend the term for an additional five years. The schedule of monthly rent was also revised to account for the extension, resulting in average annual occupancy costs equaling approximately $1.2 million per year.

On May 8, 2023, we entered into an amended supply agreement with Cordis, which require a specified minimum volume commitment from July 2023 through February 2029 based on the actual units purchased during the prior year period from July 1 through June 30, with the unit purchase price dependent upon annual volume during the same prior year period.

There have been no other material changes to our contractual obligations from those described above or in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023.

Critical Accounting Policies and Estimates

There have been no significant and material changes in our critical accounting policies during the three and six months ended June 30, 2023, 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 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023.

Recently Issued Accounting Pronouncements

See Note 3 to our condensed financial statements in Part I, Item 1 of 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

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities, credit risk, foreign currency exchange rate sensitivity and inflation risk.

Interest Rate Risk

We had cash, cash equivalents and investments of $202.2 million as of June 30, 2023 which consisted of bank deposits, money market funds, U.S. government securities, commercial paper, corporate bonds/notes, and agency bonds/notes. The primary objectives of our investment activities are the preservation of capital and support of our liquidity requirements. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our income and the fair market value of our investments. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we sell an investment before its scheduled maturity.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 10% change in interest rates would not have a material impact on the value of our cash and cash equivalents or our investments as of June 30, 2023.

We are also subject to interest rate risk from variable interest rates applicable to borrowings under our Loan Agreement in light of the variable interest rates thereunder. Any revolving loans under the Loan Agreement accrue interest at the greater of 1-month SOFR, or the Index Rate, and 0.85%, plus a margin of 3.00%. The term loans accrue interest at the greater of the Index Rate and 0.85%, plus a margin of 5.00%. The Index Rate is capped at 2.50% for purposes of the Loan Agreement. As of June 30, 2023, the aggregate outstanding principal balance under the term loan facility was $75,000,000 with the variable interest rate capped at the maximum rate of 7.50% and no amounts were outstanding under the revolving credit facility.

Credit Risk

As of June 30, 2023 and December 31, 2022, a portion of our cash and cash equivalents was maintained with Silicon Valley Bank, a division of First Citizens Bank, or SVB, and exceeded federally insured limits. Substantially all of our cash equivalents and investments reside in a custodial account held by a third party, in which SVB Asset Management is the advisor. On March 10, 2023, SVB was shut down and placed under receivership with the Federal Deposit Insurance Corporation, or FDIC, by the California Department of Financial Protection and Innovation. On March 26, 2023, the FDIC announced it had entered into a purchase and assumption agreement with First Citizens Bank & Trust Company under which all of SVB's deposits were assumed. As of the issuance date of these financial statements, we have not experienced any losses on our deposits and all of our cash deposited with SVB has been accessible to us.

As of June 30, 2023, our cash equivalents and investments are invested in highly rated money market funds, U.S. government securities, commercial paper, corporate bonds/notes, and agency bonds/notes. Uncertain financial markets, or a U.S. sovereign default or threat thereof, could result in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of securities in our investments could deteriorate and may have an adverse impact on the carrying value of these investments.

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, 2023 or December 31, 2022.

Foreign Currency Risk

Our business is conducted primarily 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.

Inflation Risk

Macroeconomic challenges in the global economy have contributed to a rising inflationary trend and impacted our cost of goods sold and selling and operating expenses, which we expect to continue into the foreseeable future. If our costs become subject to prolonged, significant inflationary pressures, we may not be able to fully offset such higher costs through price increases, which would have an adverse effect on our ability to maintain or increase our gross margin. Our inability or failure to do so could harm our business, financial condition or results of operations.

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 effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the most recent fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is 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

For information with respect to Legal Proceedings, see Note “7. Commitments and Contingencies” to our condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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 financial statements and related notes. Please also see “Cautionary Note Regarding Forward-Looking Statements.”

Summary of Principal Risk Factors

The following risks and uncertainties are among the most significant we face. However, the risks and uncertainties identified in this subsection are not the only ones we face and are qualified in their entirety by reference to all of the risk factors as further described in this Item 1A.

Risks Related to Our Business

- We have a history of net losses, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.
- We rely on, and currently sell products to enable, TCAR, which is our only product offering.
- Our business is dependent upon the continued adoption of TCAR by hospitals and physicians.
- 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.
- Global supply chain constraints and constrained labor markets have resulted and could continue to result in the inability of our suppliers to deliver finished goods, components, sub-assemblies or materials to us on a timely basis or at all.
- We rely on Cordis to supply the ENROUTE stent, and if Cordis 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.
- General macroeconomic factors, including inflation, price pressures and recessionary pressures, could increase our manufacturing costs and operating expenses or lower demand for our TCAR products and have a material adverse impact on our financial condition and results of operations.
- If we are not able to obtain or maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, 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.
- If we fail to comply with our obligations in our intellectual property license from Cordis, we could lose license rights that are important to our business.
- TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption.

- We face manufacturing risks that could adversely affect our ability to manufacture products, reduce our gross margins and negatively affect our business and operating results.
- We depend on a limited number of single-source suppliers to manufacture our components, sub-assemblies, materials and products, including Cordis, 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 face risks related to health epidemics and other outbreaks, such as possible resurgences of COVID-19 and the spread of new variants, which may negatively impact our business and operations.
- The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.
- Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

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.
- Our success depends on our ability to obtain, maintain and protect our intellectual property rights.

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.
- Our products have in the past and could in the future be subject to product recalls that could harm our reputation or increase the probability of inspection by, or additional scrutiny from, the FDA or other relevant regulatory bodies.
- Changes in the CMS fee schedules may affect our hospital customers and thereby harm our revenue and operating results.

Risks Related to Our Business

We have a history of net losses, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.

We have incurred net losses since our inception in March 2007. For the six months ended June 30, 2023, we had a net loss of $29.9 million and we expect to continue to incur additional losses in the future. As of June 30, 2023, we had an accumulated deficit of $373.7 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products. 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, investments in manufacturing and distribution capacity, and other infrastructure improvements.

Over the next several years, we expect to continue to devote a substantial amount of our resources to increase adoption of TCAR using our products, expand commercialization efforts in the United States and select international markets, improve and expand reimbursement for TCAR, conduct clinical studies, and develop additional products. No assurance can be provided that our strategic initiatives will be successful or lead us to profitability. In addition, as a public company, we incur significant legal, accounting, director and officer liability insurance and other expenses, all of which continue to increase. 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.

We rely on, and currently sell products to enable, TCAR, which is our only product offering.

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 relatively 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. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- Physician experience and hospital demand for our products and the extent of adoption of TCAR, including the rate at which physicians recommend our products and TCAR to their patients;
- Failure of our products that enable TCAR to significantly penetrate the target markets;
- Delays in, or failure to supply product, component and material deliveries by our third-party suppliers;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products and TCAR or competing products and procedures;
- Any product quality, recall, 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;
- Adequate levels of third-party coverage and reimbursement for the procedures using our products; and
- Introduction of new products, procedures or drugs for treating carotid artery disease that compete with our products and the TCAR procedure.

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 continued adoption of TCAR by hospitals and physicians.

Our future growth and profitability largely depend on our ability to increase physician awareness and adoption of TCAR and on the willingness of physicians to recommend the procedure to more of their patients. Physicians may not use 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 and increase adoption of TCAR 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 Carotid Artery Stenting, or CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- 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 or a randomized controlled trial, supporting clinical benefits;
- Familiarity and experience with Carotid Endarterectomy, or CEA, and reluctance to change to or use new products and procedures; and

- Time commitment and skill development that may be required to gain familiarity and proficiency with TCAR and our products.

In addition, it is possible that if NCD 20.7 for Percutaneous Transluminal Angioplasty is revised as proposed in the proposed decision memo released on July 11, 2023, we may experience increased competition with stents and embolic protection devices for CAS.

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 cardiologists, radiologists, neurologists, 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 who 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. If a physician experiences an adverse event in one or more of their TCAR patients or elects to convert TCAR to CEA mid-procedure, they may not continue offering and performing TCAR at the same rate or at all. Further, TCAR 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, 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, or the SVS's Vascular Quality Initiative contains real world data retrospectively comparing carotid revascularization procedures including TCAR, we have not conducted a randomized clinical trial of TCAR or head-to-head clinical trials to prospectively compare TCAR to the procedures historically available to patients, such as CEA or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis 2, or CREST-2, clinical trial currently funded by the National Institutes of Health, is ongoing and is designed to compare the effectiveness of each of CEA and CAS, in parallel randomized trials, with best medical therapy alone in standard surgical risk asymptomatic patients with carotid artery disease. We estimate that enrollment will not be completed until sometime between 2023-2024, followed by a mean follow-up period of four years. After the follow-up period post final enrollment, the trial could conclude that medical management alone achieves the same or better therapeutic results as CEA and/or CAS, which could 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 or other 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 SVS, the rate of adoption of TCAR and sales of our products that facilitate the procedure are also influenced by medical society recommendations. We believe the SVS's Clinical Practice Guidelines, or SVS Guidelines, are of importance to the broader market acceptance of TCAR. The revised SVS Guidelines on the management of carotid artery disease were published in June 2021. Like previous versions of the guidelines, the revised SVS Guidelines generally discuss CAS, and embolic protection methods, including flow reversal. The revised SVS Guidelines do state that TCAR is preferred over CEA and CAS in anatomically or physiologically high surgical risk patients, whether symptomatic or asymptomatic. If subsequent versions of the SVS Guidelines do not recommend TCAR, or if the SVS issues a negative or more limited statement regarding TCAR, physicians may not adopt or continue to use TCAR or our products at the same rate or at all, 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 adverse 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 and endovascular skills to perform the procedure. While we mandate physician attendance at our TCAR training program or training with proctors, we do not control which physicians perform TCAR or how much training they receive. 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 and other clinical trials, studies or registries of TCAR. 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. Additionally, hospitals and physician organizations may adopt physician credentialing guidelines requiring TCAR training that is more extensive than our training program. If physicians conclude that we do not provide adequate TCAR training, they may be less likely to adopt TCAR and our products, which could have a material adverse effect on our business, financial condition and results of operations.

Global supply chain constraints and constrained labor markets have resulted and could continue to result in the inability of our suppliers to deliver finished goods, components, sub-assemblies or materials to us on a timely basis or at all, which would adversely affect our business, financial condition and results of operations.

We may not be able to maintain an adequate supply of the components, sub-assemblies and materials that are used to manufacture our TCAR products as well as to support our research and development activities for new products. For example, certain liners and shrink tubing components used in both the ENROUTE stent and the ENROUTE NPS have been in short supply and delivery of these materials have been delayed from time to time, which could result in manufacturing delays for our TCAR products. In particular, we have increasingly become concerned with the ability of a critical supplier of certain polymer tubing materials used in our products to provide our third party manufacturer these polymer tubing materials on a timely basis. If this supplier is unable to provide these polymer tubing materials on a timely basis, it could result in TCAR product delays to our customers, which, in turn, would adversely affect our results of operations. Similarly, we rely on Lake Region Medical for our supply of guidewires and Nordson Medical for our balloon catheters, which have also been in short supply from time to time. If there were a shortage of supply, the cost of components, sub-assemblies and materials may increase or we may need to pay a premium to obtain sufficient supply, either of which could harm our ability to provide our products on a cost-effective basis or at all, or we may experience delays in providing our TCAR products to our customers. We also may experience delays in and increased costs for our research and development programs and clinical trials due to the inability to obtain the necessary materials to advance these programs and trials. In connection with any supply shortages, reliable and cost-effective replacement sources may not be available on short notice or at all, and this may force us to increase prices and face a corresponding decrease in demand for our TCAR products, or force us to absorb these increased costs. Our suppliers may also be impacted by supply or labor shortages which may delay or impact the availability of the components, sub-assemblies and materials needed to manufacture our TCAR products. In the event that any of our suppliers experience supply or labor shortages, delays, or were to reduce, or discontinue, production of our key product components, sub-assemblies or the materials used in our TCAR products, developing alternate sources of supply for these items would be time consuming, difficult and costly. If we or one of our suppliers were to experience a supply shortage with our components, sub-assemblies and the materials or labor necessary to manufacture our TCAR products our reputation in the market, demand for our TCAR products and our operating results may be significantly and adversely affected and new products may be delayed.

We rely on Cordis to supply the ENROUTE stent, and if Cordis 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 Cordis to manufacture the ENROUTE stent pursuant to a supply agreement, and as such, Cordis is our sole supplier of this product. While we strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, no assurance can be provided that this strategy will be sufficient. If we were to experience a shortfall or issue with the supply of ENROUTE stents by Cordis, we estimate that it would take up to two years or more to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for a different carotid stent. In addition, Cordis currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. This facility has previously and in the future could become subject to a COVID-19 outbreak which would cause Cordis to temporarily shut down manufacturing operations, which would in turn present risk to the ongoing supply of our stents used in TCAR procedures. If Cordis's ability to manufacture the ENROUTE stent is interrupted as a result or for any other reason, including, for example, its inability to obtain necessary or sufficient components or products from other third parties, or if Cordis experiences a product recall, cash flow or liquidity issues or 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.

General macroeconomic factors, including inflation, price pressures, and recessionary risks, could increase our manufacturing costs and operating expenses or lower demand for our TCAR products and have a material adverse impact on our financial condition and results of operations.

The risk of a sustained economic downturn or recession and other macroeconomic factors could adversely affect customer demand for our TCAR products. We continuously monitor the effects of inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, which may adversely affect our results of operations. Specifically, we are experiencing inflationary and price pressures and increased labor costs and labor and staffing shortages, affecting the cost of the components for our TCAR products and the wages that we pay our employees, as well as the wages our vendors pay their employees, due to challenging labor market conditions. Competitive, macroeconomic and regulatory conditions restrict our ability to fully recover, such as increased costs through price increases, higher costs of acquired goods and services resulting from inflation, other drivers of cost increases or reduced demand for TCAR products. We may be unable to pass these increased costs along to our customers or fully offset the impact of persistent inflation or a recession. Our inability or failure to do so could have a material adverse effect on our business, financial condition and results of operations or cause us to need to obtain additional capital earlier than anticipated.

If we are not able to obtain or maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, 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, or CMS, under a National Coverage Determination, or NCD, 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, Veterans' Administration, 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 or limit coverage for products and procedures or delay coverage approval until further clinical data are available. As a result, the coverage determination, technology assessment, and coverage reconsideration processes are often time-consuming and costly processes 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 TCAR procedures using our products, or if there is any decline in the amount that payers are willing to reimburse our customers for TCAR, new customers may not adopt, or may reduce their rate of adoption of, our products and we could experience additional pricing pressure, any of which could have a material adverse effect on our business, financial condition and results of operations.

Products for carotid stenting including our TCAR products are covered for Medicare beneficiaries under certain circumstances under NCD 20.7 for Percutaneous Transluminal Angioplasty. Coverage for non-Medicare patients depends upon commercial and other payer policies. Based on reimbursement information regarding CAS from IBM® MarketScan® Inpatient View, we estimate that approximately 75% of carotid procedures are reimbursed by CMS and the remaining approximately 25% are reimbursed by commercial and other payers. The Medicare program is administered by CMS and the Medicare Administrative Contractors, or MACs, which make determinations regarding Medicare hospital and physician coverage and payment. CMS reimburses hospital inpatient services based on Medicare Severity Diagnosis Related Groups, or MS-DRGs. All CAS, TCAR and CEA procedures are currently paid only as Medicare inpatient procedures. CMS's policy focus on hospital price transparency, site (e.g. inpatient, outpatient, ambulatory surgery center and office) neutral payments and MS-DRG refinements may place additional downward pressure on future hospital inpatient payments. Medicare payments to physicians are based on a Resource Based Relative Value System. CMS's policy changes to adjust or reallocate reimbursement between primary care services and specialty services may result in reductions in the payment rate for procedures involving our products. As a result of any reductions in payments to hospitals and physicians for TCAR procedures, TCAR utilization may decline, which would have a material adverse effect on our business, financial condition and results of operations. 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, are 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.

Any current or future reconsideration of the applicable Medicare NCD 20.7 – Percutaneous Transluminal Angioplasty could result in expansion of coverage of carotid stenting procedures including TCAR based on FDA-approved indications or continued or additional coverage limitations, including a requirement to participate in CMS-approved investigational studies. CMS's NCD that covers TCAR and CAS is subject to change based upon the availability of new trial data and other clinical data as well as the development and availability of new medical devices and medical procedures in this space, including the medical community's current understanding of patient selection and operator experience and their impact on periprocedural complications, among other factors that can impact patient outcomes. In particular, the comparative benefits of various revascularization procedures and medical devices to prevent future strokes in symptomatic and asymptomatic carotid stenosis patients as well as ways to optimize patient outcomes are subject to ongoing and continuous review and clinical evaluation. For example, in January 2023, CMS accepted a formal request from the Multispecialty Carotid Alliance to expand Medicare beneficiary access for carotid artery stenting with embolic protection in patients at high risk and standard risk for CEA with asymptomatic carotid artery stenosis ≥ 70% and symptomatic carotid artery stenosis ≥ 50%, including the removal of facility or operator requirements. We submitted comments to CMS prior to the initial 30-day public comment period on the NCD closing on February 11, 2023. Submitted comments are available on the CMS website. The proposed decision memo was released on July 11, 2023 with a public comment period ending on August 10, 2023. In the proposed decision memo, CMS proposes that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a FDA approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries in patients with symptomatic carotid artery stenosis ≥50% and in patients with asymptomatic carotid artery stenosis ≥70%; provided, that: (1) independent neurological assessment before and after CAS must be performed to assess procedural risks; (2) evaluation of the extent and severity of carotid artery stenosis must use one of the following non-invasive modalities for first-line imaging: duplex ultrasound, computed tomography angiography, or magnetic resonance angiography; and (3) prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary, which shared decision-making interaction must involve the use of a validated shared decision-making tool and include: (i) discussion of all treatment options for carotid stenosis to ensure the beneficiary is familiar with and aware of all treatment options including, but not limited to, procedures that fall within the parameters of this NCD; (ii) explanation of risks and benefits for each option specific to the beneficiary's clinical condition; (iii) integration of clinical guidelines (e.g., patient life-expectancy); and (iv) discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan. CMS is expected to complete its review of public comments and issue a final National Coverage Determination 20.7 on or before October 10, 2023. If the NCD is consistent with the proposed decision memo, it is possible that that we may experience increased competition. To the extent the medical community's or CMS's views change regarding TCAR, CAS and CEA procedures, either individually or in comparison to each other, on issues of safety and effectiveness, operator experience, or patient selection or qualifications for coverage and reimbursement under the NCD, the demand for our TCAR products could be materially impacted. Therefore, we can provide no assurance that the coverage and reimbursement, market share and demand, and/or revenues for any of our products will be maintained.

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 TCAR or 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 Cordis, we could lose license rights that are important to our business.

We are a party to a license agreement with Cordis, under which Cordis has granted us a worldwide, non-exclusive, perpetual, royalty-bearing license, without the right to sublicense, 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. Our license agreement with Cordis 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 Cordis, 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, elimination or expiration of our licensed rights under it or any other license or agreement, 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 new licenses for different stents. 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.

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 surgical and 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. Risks of using our products in TCAR include risks that are common to surgical and endovascular procedures and are detailed in the FDA-approved and FDA-cleared labeling. Major adverse events associated with all carotid interventions include stroke, heart attack and death. These risks may prevent widespread market adoption in the absence of adequate physician training on our products and in appropriate patient selection.

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. Our ENROUTE Enflate RX Balloon Dilatation Catheter is contraindicated for use in coronary arteries. Generally, further contraindications include, but may not be limited to: patients with highly calcified lesions resistant to PTA; patients with a target lesion with a large amount of adjacent acute or sub-acute thrombus; patients with uncorrected bleeding disorders; and patients that have not been anti-coagulated. Additionally, patients who lack at least five centimeters of common carotid artery free of significant disease are not indicated for our ENROUTE NPS.

We face manufacturing risks that could adversely affect our ability to manufacture products, reduce our gross margins and negatively affect our business and operating results.

Our business strategy depends on our ability to manufacture, and our contract manufacturers’ 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 facilities located in Sunnyvale, California, and in Plymouth, Minnesota, where we currently assemble and package certain of our products, and inspect, release and ship all of our products. If our or our manufacturing partners' facilities 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 or our manufacturing partners' inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;

- Our or our manufacturing partners' inability to maintain compliance with quality system requirements or pass regulatory quality inspections;

- Our or our manufacturing partners' failure to develop products in a timely manner or to required specifications or to increase production capacity or volumes to meet demand;

- Our or our manufacturing partners' 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.

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 or our manufacturing partners 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 or our manufacturing partners' 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 or our manufacturing partners to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current gross 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, materials and products, including Cordis, 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, such as our ENROUTE stent and for certain key components, sub-assemblies and materials for our ENROUTE NPS**.** In addition, we rely on Lake Region Medical to supply our guidewires and Nordson Medical for our balloon catheters. 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 for some 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 manufacturing partners, including Cordis, rely on single-source suppliers as well, and are subject to the foregoing risks.

Our and our manufacturing partners' 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 due to global supply chain constraints or other factors;
- Difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- Inability of suppliers to comply with applicable provisions of the FDA's Quality System Regulation, or QSR, or other applicable laws or regulations enforced by the FDA and other state and applicable regulatory authorities;
- Inability to adequately ensure the quality of products and components manufactured by third parties;
- Production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- Delays in delivery by our suppliers due to changes in demand from us or their other customers;
- Delays or inability of suppliers to provide products and components due to cash flow or liquidity issues; and
- An outbreak of disease or similar public health threat, such as the ongoing threat of new COVID-19 variants, particularly as it may impact our supply chain.

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. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. Our decision to recall these lots was based on complaints we received about tips detaching from the stent delivery system as well as internal testing that we conducted. We determined the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, have to purchase replacement products, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted.

We face risks related to health epidemics and other outbreaks, such as the COVID-19 pandemic and the spread of new variants, which may negatively impact our business and operations.

Our business could be adversely impacted by the effects of health epidemics and other outbreaks, such as the COVID-19 pandemic and the spread of new variants, or COVID-19, including through:

- Postponement of TCAR procedures by physicians or their patients in response to COVID-19 or the diversion of resources to treat patients with COVID-19 or other conditions deemed higher priority;
- Hospital staffing shortages which may result in fewer diagnoses and a lower number of TCAR procedures performed;
- Restrictions on hospital capacity, or other resource constraints, such as the availability of contrast dye, that may cause problems for hospitals scheduling or rescheduling TCAR procedures;
- Limitations in hospital or employee resources that would otherwise be focused on performing TCAR procedures;
- Patients who may be reluctant to visit their physicians at their offices or in hospitals due to fear of contracting COVID-19;
- Physicians not performing as many diagnostic tests for their patients and closures, staffing shortages, or reduced hours of the labs where these tests are performed, even where physicians continue to treat symptomatic patients, treatment of asymptomatic patients is being deferred in many cases in areas where COVID-19 cases and

hospitalizations are significant, which has translated into fewer than expected TCAR procedures being performed throughout various periods of the pandemic;

- Delays in enrollment in clinical trials across the medical device industry which may affect any new trials we are pursuing or decide to pursue, including our ROADSTER 3 trial, which is related to our standard surgical risk post-approval study, and our Neuroprotection in Transcarotid Embolectomy, or NITE-1, trial, which is related to one of our stroke treatment products under development;

- Governmental mandates related to COVID-19 or other infectious diseases, which have impacted, may continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and/or reduce our margins. An extended implementation of governmental mandates could impact our ability to operate effectively and conduct ongoing manufacturing or research and development activities. However, we are considered an essential business under applicable state rules and our manufacturing operations to date are ongoing;

- Delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;

- Unavailability of key personnel or large groups of our employees due to contracting a virus, such as COVID-19;

- Intermittent travel restrictions and restrictive hospital policies impacting our sales professionals and therapy development specialists who support them;

- Competition for operating room and hybrid operating rooms within hospitals that are resource constrained or have dedicated certain resources only to COVID-19 patients;

- The spread of new virus variants and varying infection and related hospitalization rates which increase the volatility and uncertainty in the expected number of TCAR procedures and demand for our products;

- Hospitals cancelling and deferring elective surgeries, which reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as they seek cost savings;

- Hospitals having issues with cash flow or ceasing doing business due to the impact of COVID-19 on their operations, which could reduce the number of hospitals where TCAR is performed and adversely affect our ability to collect amounts due to us and our revenue as a result;

- The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion has also delayed preparation for and launch of such expansion efforts;

- Delayed regulatory timelines for approval in some countries;

- Prolonging existing restrictions related to COVID-19 that have impacted the number of TCAR procedures performed;

- Hospitals restricting or limiting access for non-patients, including our sales professionals and therapy development specialists, which has negatively impacted our access to physicians and their staff; or

- Members of our field team may choose not to enter hospitals due to preexisting conditions, personal choice, or on doctors' orders or may be unable to enter hospitals due to hospital policy, although they continue to be available to support TCAR procedures, either in person or virtually.

The extent to which COVID-19 will continue to impact our business will depend on future developments, which are uncertain and cannot be predicted, including indirect impacts on the labor market and the operations of our business as well as the operations of our contractors, partners, and our customers. Although President Biden announced that the administration ended the COVID-19 national and public health emergencies on May 11, 2023, the full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations is unclear.

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, violence, 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.

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 manufacturing partners 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 would be negatively affected by many factors, including our rapid growth, product recalls, pandemics, 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, changes to hospital capacity, staffing, procedure and protocol changes, 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. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements and our manufacturing may be affected by potential resurgences of COVID-19 and other macroeconomic forces on our suppliers. We are working to increase our inventory on hand in reaction to global supply chain constraints, but these inventory levels may prove to be inadequate. If we do not have adequate supply of components, sub-assemblies and materials there may be interruptions, delays or cancellations of deliveries of our TCAR products 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 our manufacturing partners, or at all, and our manufacturing partners 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, net income or net loss 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.

Our actual operating results may differ significantly from our guidance, which could cause the market price of our common stock to decline.

From time to time, we release guidance regarding our future performance, such as our anticipated annual revenue, that represents our management's estimates as of the date of release. This guidance, which consists of forward-looking statements, is prepared by our management and is qualified by, and subject to, the assumptions and the other information contained or referred to in the release. Our guidance is not prepared with a view toward compliance with published guidelines of the American Institute of Certified Public Accountants, and neither any independent registered public accounting firm nor any other independent expert or outside party compiles, examines or reviews the guidance and, accordingly, no such person expresses any opinion or any other form of assurance with respect thereto.

Guidance is based upon a number of assumptions and estimates that, while presented with numerical specificity, is inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. We generally state possible outcomes as high and low ranges which are intended to provide a sensitivity analysis as variables are changed but are not intended to represent that actual results could not fall outside of these ranges. The principal reason that we release this data is to provide a basis for our management to discuss our business outlook with analysts and investors. We do not accept any responsibility for any projections or reports published by any such persons.

Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions of the guidance furnished by us will not materialize or will vary significantly from actual results. Accordingly, our guidance is only an estimate of what management believes is realizable as of the date of release. Actual results will vary from the guidance and the variations may be material. Investors should also recognize that the reliability of any forecasted financial data will diminish the farther in the future that the data are forecast. In light of the foregoing, investors are urged to put the guidance in context and not to place undue reliance on it.

Any failure to successfully implement our operating strategy or the occurrence of any of the events or circumstances set forth in this Quarterly Report on Form 10-Q could result in the actual operating results being different than our guidance, and such differences may be adverse and material. The failure to achieve such guidance could disappoint investors and analysts and cause the market price of our common stock to decline.

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. The safety and effectiveness of certain products for 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 NPS sheath. In addition, per the FDA-approved labeling for the ENROUTE stent, TCAR is limited to certain threshold degrees of stenosis depending on symptom and surgical risk status. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions or severe vessel tortuosity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market.

Expanding the addressable market for TCAR is dependent upon reimbursement expansion initiatives, favorable data from any post-approval study we or other researchers conduct, and obtaining and maintaining coverage and adequate reimbursement for any new product approvals.

In May 2022, we announced FDA approval of a label expansion for the ENROUTE stent for use in standard surgical risk patients. In June 2022, we announced that CMS, through collaboration with the SVS's Patient Safety Organization and their Vascular Quality Initiative, or VQI, has expanded coverage for TCAR to include standard surgical risk patients within the VQI's TCAR Surveillance Project. As a condition of FDA approval for such label expansion, we are conducting a prospective, multi-center, single-arm post-approval study, ROADSTER 3, to assess real-world treatment of standard surgical risk patients with carotid artery disease using TCAR and announced enrollment of our first patient in September 2022. If the ROADSTER 3 study or other studies conducted by independent researchers or organizations, or complaints or other reports from our customers or patients, reveal a higher rate of adverse events or other unexpected safety or efficacy concerns, FDA may restrict or withdraw the label expansion approval. Any future report or publication raising any material safety or efficacy concerns regarding any of our approved products or approved uses may cause CMS or other payors to modify or restrict their coverage and reimbursement policies for our products and related procedures. If any of these events were to occur, or if we fail to demonstrate continued safety and efficacy for our approved products and their indications, 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 the TCAR procedures using 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 reduces market prices for our products and/or require administrative fees, thereby reducing our revenue and/or 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 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 a portion of our manufacturing, warehouse, research and development and non-field-based sales, general and administrative operations in a building located in Sunnyvale, California, which is situated on or near earthquake fault lines. We have redundant manufacturing for our ENROUTE NPS at our Plymouth, Minnesota facility. Should either of our facilities be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, including climate change-related severe weather or disasters, it could take extensive time to relocate or rebuild, during which time our employees may seek other positions and our research and development would cease or be delayed. 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, losses caused by earthquakes, losses we may suffer due to our products being replaced by competitors' products or loss in value due to associated decreases in our stock price. The inability to perform our research and development 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 facilities could have a material adverse effect on our business, financial condition and results of operations.

In addition, we rely on our manufacturing partners to supply certain of our products, and our partners are subject to similar risks with respect to their facilities. If our manufacturing partners' facilities are damaged or destroyed and their ability to supply products to us is limited, it could negatively affect our reputation, physician relationships and TCAR adoption, all of which could have a material adverse effect on our business, financial condition and results of operations. Several of our products are sterilized at a particular third-party facility, with limited alternate facilities. If an event occurs that results in damage to or closure of one or more of such facilities, we may be unable to sterilize such products at the previous levels or at all. Because of the time required to approve and license a sterilization facility, a third party may not be available on a timely basis to replace capacity in the event sterilization capacity is lost.

If we fail in our training initiatives, to increase our sales and marketing capabilities or to develop broad brand awareness, our growth will be impeded and our business will suffer.

We currently rely on our direct sales force to sell our products in targeted geographic regions in the U.S., 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 and clinical 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 and clinical expertise and qualifications, or if we are unable to successfully instill such technical and clinical expertise in replacement personnel, our revenues and results of operations could be materially harmed. The hiring and training of new sales personnel takes time and could adversely affect our sales and financial results for a particular period, as could changes in our sales territories and sales structure. During first quarter of 2023, we hired several new sales personnel, created new sales leadership positions, re-balanced certain geographic territories and created new territories which while intended to and will likely increase our touch points with physicians had a disruptive effect, to some extent, on our first quarter 2023 revenues.

In order to generate future growth, we plan to continue to expand and leverage our sales, marketing, and medical affairs infrastructure to increase our trained physician and hospital customer base and our business. Identifying and recruiting qualified sales, marketing and medical affairs 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 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 medical affairs department may not train physicians at a rate sufficient to expand our physician base in a manner consistent with our business plan. 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 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. 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 and proximal embolic protection devices, guidewires, balloons and sheaths. Such companies include Abbott, Boston Scientific, Cook, Cordis, Medtronic, Terumo, Gore, Contego Medical and InspireMD. These technologies, other products that are in ongoing 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. In addition, physicians may choose to use products not labeled for TCAR in an off label fashion and competitive companies may promote their CAS products for off-label use in TCAR.

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 and other treating specialties, 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.

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 improving existing products for TCAR, developing new products for TCAR, and developing new products for other disease states beyond carotid artery disease. For example, following receipt of 510(k) clearance from the FDA in September 2022, we initiated a limited market release of our ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter in the fourth quarter of 2022 and a full market release during the second quarter of 2023. 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.

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

Our business is subject to significant risks associated with the 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. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and 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 bleeding, arterial dissection, cranial nerve injury, myocardial infarction, 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 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.

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 patients, or they experience adverse events, it could discourage patients from referring TCAR to others. For example, although we have not received any reports of strokes, deaths or other long-term patient sequelae from the tip detachments that triggered our recent recall, if there were to be patient injury, dissatisfied patients may express negative opinions through social media or we may otherwise suffer reputational damage or become subject to product liability lawsuits. Any failure to meet patient expectations and any resulting negative publicity or lawsuits 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 and Chief Operating 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 Chief Commercial Officer, are critical to driving the growth in sales of our products. Any of our employees may terminate their employment with us at any time. A prolonged and significant decline in the value of long term incentives could also negatively impact our ability to retain key employees. 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, 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 along with salary, benefits and other factors. If the perceived benefits of our stock awards decline, either because we 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.

The ENROUTE stent has been approved by the FDA for the treatment of 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, myocardial infarction and death, potentially leading to product liability claims. 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, contain 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.

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, general and administrative personnel, manufacturing and distribution operations, and facilities and information technology, or IT, and 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 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.

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 and investments, together with our expected revenue, 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;
- Restructuring, refinancing or repayment of debt and any default by the U.S. government on its debt which could have broad macroeconomic effects that could, among other things, raise our borrowing costs;
- The scope and timing of investment in our sales force, marketing initiatives and physician training programs;
- The scope, rate of progress and cost of our research and development activities, current or future clinical studies and additional regulatory clearances or approvals;
- The scope and timing of investment in acute ischemic stroke and other neurovascular and cardiac products we may develop;
- The costs associated with any future 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, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, 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, 2023, we had an aggregate of approximately $75.0 million in principal outstanding under our Loan Agreement with Oxford Finance. We must make significant interest-only monthly payments under the Loan Agreement, and the term loans outstanding under the Loan Agreement will begin to amortize in equal monthly installments beginning in July 2026 (unless we elect to extend the interest-only period by another year), which will divert resources from other activities. Our obligations under the Loan Agreement are collateralized by substantially all of our assets and we are subject to customary affirmative and negative covenants, including covenants limiting our ability and the ability of our subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type. The covenants related to the 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 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 Loan Agreement to become immediately due and payable, termination of commitments to extend further credit, a 5% increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement. 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.

Adverse developments with respect to the stability of financial institutions we do business with, or unstable banking, credit and/or capital market conditions generally, or the perception thereof, could adversely affect our ability to access cash, obtain additional financing, restructure or refinance our indebtedness, or meet our liquidity and debt service requirements.

The recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure could materially and adversely affect our liquidity, financial condition, results of operations, business and stock price. The recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC, has created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, and such access to date by us to our cash and cash equivalents held at SVB has been uninterrupted, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. As of June 30, 2023 and December 31, 2022, a portion of our cash and cash equivalents was maintained with SVB and exceeded federally insured limits. Substantially all of our cash equivalents and investments reside in a custodial account held by a third party, in which SVB Asset Management is the advisor. As of the issuance date of this Quarterly report on Form 10-Q, we have not experienced any losses on our deposits and all of our cash deposited with SVB has been accessible to us, although no assurance can be provided that we will not experience any future losses on our deposits or access to our cash equivalents and investments. As of June 30, 2023, our cash equivalents and investments are invested in highly rated money market funds, U.S. government securities, commercial paper, corporate bonds/notes, and agency bonds/notes. Uncertain financial markets, or a U.S. sovereign default or threat thereof, could result in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of securities in our investments could deteriorate and may have an adverse impact on the carrying value of these investments. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank or lender that has failed or is otherwise distressed or if other banks and financial institutions enter receivership or become insolvent in the future, we may experience delays or other issues in accessing our cash and meeting our financial obligations. In addition, any future unstable banking, credit and/or capital market conditions could also adversely affect our ability to obtain additional financing, restructure or refinance our indebtedness, if needed, or meet our liquidity and debt service requirements or the ability of our suppliers, vendors, customers and others in which we do business to do any of the foregoing with respect to their respective businesses.

We may acquire other companies or technologies, or enter into license agreements, distribution arrangements or strategic partnerships, which could fail to result in a commercial product or generate 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, we may in the future seek to acquire, license or invest in businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We could also seek to enter into distribution arrangements or strategic partnerships with third parties that we believe could increase our revenue or offer other commercial benefits. However, we cannot assure you that we would be able to successfully complete any acquisition, license agreement or distribution agreement we choose to pursue, or that we would be able to successfully integrate any business or product or technology in a cost-effective and non-disruptive manner. Similarly, we cannot guarantee that we would derive benefits from any distribution arrangement or other strategic partnership. The pursuit of potential acquisition, license or partnering opportunities may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable transactions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or strategic partners, or be successful in entering into an agreement with any particular target or partner, or obtain the expected benefits of any acquisition, license, investment or other strategic partnership arrangement.

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, product or technology fails to meet our expectations, our operating results, business and financial condition may suffer.

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

As of December 31, 2022, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $320.1 million and $271.5 million, respectively. Our U.S. federal NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2027 (U.S. federal NOLs, and certain state NOLs, arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028. We may use these NOLs to offset taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions may limit the NOLs we may use in any year for U.S. federal and state income tax purposes in the event of certain changes in ownership of our company. An ownership change pursuant to Section 382 of the Code 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. We completed a 382 study of our historic ownership changes through December 31, 2022 and determined there are limitations on the use of our loss and credit carryforwards. 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 income 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. Furthermore, U.S. federal NOLs arising in tax years beginning after December 31, 2017 may only be used to offset 80% of our taxable income. This change may require us to pay U.S. federal income taxes in future years despite generating a loss for U.S. federal income tax purposes in prior years. Limitations under state law may differ.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers or 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, store, or otherwise process 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 and process sensitive intellectual property and other proprietary business information. We rely 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, and they also face numerous security threats. 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.

Although we take measures designed to protect sensitive information from unauthorized access or disclosure, our IT and infrastructure, and that of our technology partners and third parties on which we rely, may be vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by employees and/or other third parties, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks or the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets. 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 and the third parties on which we rely may be more susceptible to security breaches and other security incidents due to many of our employees and employees of our third-party service providers working remotely for some portion of time. Also, Russia's war with Ukraine may subject us and third-party service providers to heightened risks of cybersecurity incidents and security and privacy breaches, including attacks that could materially disrupt our research and development programs or other aspects of our operations. We continue to invest in cybersecurity solutions, highly-qualified security personnel and managed security services with respect to our data and IT in an effort 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, or incidents or compromises impacting, our third-party providers' databases, systems, or other IT or infrastructure.

Any system or other IT failure, accident or security breach or incident that causes interruptions in our own or in our third-party service providers' operations, or results in data loss, corruption, or unavailability, could result in a material disruption of our research and development programs or other aspects of our operations. In addition, if any disruption or security breach or incident results in loss, destruction, alteration, or unavailability of, or damage or unauthorized access to, our data or applications or unauthorized access to, disclosure, dissemination or other processing of confidential or proprietary information that we or our third-party service providers process, including personal information, we may incur liability as a result, our research and development programs and competitive position may be adversely affected. Any such disruption, failure or security breach or incident could also cause us to incur additional costs to respond to and otherwise address such disruption, failure or security breach or incident. In the event of any such disruption, failure or security breach or incident, or any perception that one has occurred, we could be exposed to claims, demands, and litigation from private parties, and governmental investigations and other proceedings and we could be subject to significant fines or penalties. As a result of a new SEC rule on cybersecurity disclosure, we will be required to disclose, on a current basis pursuant to new Item 1.05 of SEC Form 8-K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations. We will also be required to describe, on a periodic basis, our processes, if any, for the assessment, identification, and management of material risks from cybersecurity threats, and describe whether any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition, our board's oversight of risks from cybersecurity threats and management's role in assessing and managing material risks from cybersecurity threats. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident and to comply with this new SEC cybersecurity rule.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

Our long-term strategy is to increase our international presence, including but not limited to securing regulatory approvals and reimbursement in Japan and China. For example, in the fourth quarter of 2022, we received approval from the Japan Association for the Advancement of Medical Equipment for our ENROUTE NPS and ENROUTE stent. In addition, in the first quarter of 2023, we received approval from China's National Medical Products Administration for our ENROUTE NPS. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international distributors, providers and 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 our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with obtaining and maintaining adequate reimbursement for our products and managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Difficulties in adequately training and managing international distributors;
- 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.

Additionally, pursuant to the terms of our existing intellectual property license and supply agreement with Cordis, there are certain restrictions on our ability to sell the ENROUTE stent through select direct competitors of Cordis. If we are unable to locate international distributors that are not select direct competitors to Cordis, to market and sell our ENROUTE stent, our ability to expand our business internationally may be harmed, which could have a material adverse effect on our business, financial condition and results of operations.

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 recently completed the process of further enhancing policies and procedures with the intent 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.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants, independent contractors, and commercial partners.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with governmental laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCPA or a similar state law, or the impact of such actions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

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 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 some 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 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 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, trademarks or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents, trademarks 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 depends 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 depends, 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.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. We cannot assure that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign-issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. 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."

Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties or could prevent us from manufacturing, selling or using the product, any of which could severely harm our business.

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 may 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 research and development or 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 sufficient patent protection 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.

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 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.

Further, the Leahy-Smith Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we, our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

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.

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 and managing through regulatory implications such as relabeling. 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. In other cases, our competitors may associate our marks, such as TCAR, with their products and infringe upon our intellectual property as a result. 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:

- 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.

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. Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. It is unclear how the other healthcare reform measures of the Biden administration or future litigation will impact the ACA or our business.

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 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of March 31, 2022, unless additional Congressional action is taken. Under current legislation, starting on April 1, 2022, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester.

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 which began 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 and other countries where we may decide to commercialize could have similar effects.

Our products have in the past and could in the future be subject to product recalls that could harm our reputation or increase the probability of inspection by, or additional scrutiny from, the FDA or other relevant regulatory bodies.

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 has occurred, and could occur again in the future, as a result of component failures, manufacturing errors or design or labeling defects. In January 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System. Additional recalls of our products would divert managerial attention, be expensive, harm our reputation with customers, result in additional scrutiny from the FDA or other relevant regulatory bodies and harm our financial condition and results of operations. Additional recall announcements could also negatively affect our stock price.

Changes in the CMS fee schedules may affect our hospital customers and thereby 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 per 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 and imprisonment. 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 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 applicable 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 and other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding 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 with additional amounts 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; and

- 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, and, in certain circumstances, criminal penalties including fines 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.

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 if 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 planned 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.

Changes in tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

We are subject to tax laws, regulations, and policies of the several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions and/or our tax liabilities. For example, in August 2022 the United States enacted a 1% excise tax on stock buybacks and a 15% alternative minimum tax on adjusted financial statement income for certain large corporations as part of the Inflation Reduction Act of 2022. Further, many countries, and organizations such as the Organization for Economic Cooperation and Development have proposed implementing changes to existing tax laws, including a proposed 15% global minimum tax. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. There can be no assurance that our effective tax rates, tax payments, or tax credits and incentives will not be adversely affected by these or other developments or changes in law.

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, including our FDA approved Investigational Device Exemption, or IDE, for our feasibility study in acute ischemic stroke, NITE-1, 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.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In September 2019, the FDA issued revised final guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market, or distribute our products. The FDA’s and other regulatory authorities’ policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay regulatory clearance or approval of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation, or policies, when and if promulgated, enacted, or adopted may have on our business in the future. 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.

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. For example, as a condition of the FDA approval for the label expansion for ENROUTE stent to include patients at standard risk for adverse events from carotid endarterectomy, in September 2022, we announced the enrollment of the first patient in ROADSTER 3, our prospective, multi-center, single-arm study to assess real-world treatment of standard surgical risk patients with carotid artery disease using TCAR. 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. As discussed above, findings of meaningfully higher rates of adverse events or any unexpected safety or efficacy concerns related to our approval products in such post-approval study or any other independent studies or reports can result in FDA withdrawal or restriction of our PMA approval, which can have a material adverse effect on our business prospects, reputation, and market acceptance of our products.

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 have a robust post-market surveillance and complaint handling system which provides for timely communication between our field employees and customers and our internal Quality Assurance team. Information regarding our products and user and patient experiences is reviewed and, where appropriate, regulatory authorities are notified. Adverse events and device malfunctions are reported in the United States to the FDA and publicly listed in the Manufacturer and User Facility Device Experience (MAUDE) database.

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 an additional inspection by, or increased scrutiny from, 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. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted.

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. 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. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- Patients do not enroll in clinical trials at the rate expected;
- Patients do not comply with trial protocols;
- Patient follow-up is not at the rate expected;
- Patients experience adverse events;
- Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- Device malfunctions occur with unexpected frequency or potential adverse consequences;
- Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- Institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- Third-party investigators are disqualified by the FDA;
- We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- Changes in government regulations or administrative actions;
- The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

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. In July 2022, we voluntarily requested the cancellation of our CE Mark certifications for business reasons but will continue to work with our Certified Body to maintain ISO 13485:2016 certification. The CE Certificates were cancelled, effective August 23, 2022, but the ISO 13485:2016 certification remains in effect. We may seek new CE Mark certifications in the future.

If we, or our suppliers, fail to comply with the FDA's QSR, 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 QSR, 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. 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 and state authorities. 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, manufacturer and complaint file establishment. 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, 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. If the FDA or CDPH 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.

Inadequate funding for the FDA, the SEC, the CMS and other government agencies as a result of a U.S. federal government shutdown could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in the past as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Environmental, social and corporate governance, or ESG matters, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders on ESG matters including climate change, energy and water use, plastic waste and other sustainability concerns. Additionally, public interest and legislative pressure related to public companies' ESG practices, including rules related to climate change and climate-related disclosures, continue to grow. For example, in 2022, the SEC published a proposed rule that would require companies to provide significantly expanded climate-related disclosures at significant costs and operational impacts to comply and impose increased oversight obligations on our board of directors and management.

If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, diversity in our employee base or on our board of directors, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single-use and non-recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs.

If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our company, and customers and consumers may choose to stop purchasing our products, which could have a material adverse effect on our reputation, business or financial condition.

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 can be highly volatile and may fluctuate substantially due to many factors, including, without limitation:

- Analysts' estimates, investors' perceptions, recommendations by securities analysts, the loss of analyst coverage 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 and business 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, including deteriorating market conditions due to investor concerns regarding inflation, interest rate and economic policies, supply chain issues, geopolitical tensions including the war between Russia and Ukraine and changes in China-Taiwan relations;
- Changes in reimbursement by current or potential payers, including CMS's decision to reconsider NCD 20.7, Percutaneous Transluminal Angioplasty, that provides coverage stipulations for CAS and TCAR;
- 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 as well as studies and registries conducted by others using our products;
- The results of clinical trials that study competing carotid interventions or medical management of carotid artery disease;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls, backorders 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.

We are obligated to 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 in our annual report on Form 10-K each year. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are also required to comply with, among other requirements, the auditor attestation requirements of Section 404 in our annual report on Form 10-K each year. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We have engaged outside consultants who function in the capacity of an internal audit group, and we plan to continue to hire additional consultants, accounting and financial staff with appropriate public company experience and technical accounting knowledge as we maintain the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

We cannot assure you that there will not be material weaknesses 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 our current and any future 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.

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:

- 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.

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 arising pursuant to any provision of the Delaware General Corporation Law or our amended restated certificate of incorporation or bylaws (as either may be amended from time to time), or (4) any 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. Unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act against any person in connection with any offering of our securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person or other defendant. 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 securities 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.

Our business or the value of our common stock could be negatively affected as a result of actions by activist stockholders.

We value constructive input from our stockholders, and our Board of Directors and management team are committed to acting in the best interests of our stockholders. However, stockholders may from time to time engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes or acquire control over the Company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of our Board of Directors and senior management from the pursuit of business strategies. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, employees, and joint venture partners, and cause our stock price to experience periods of volatility or stagnation.

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 common stock.

We have never paid cash dividends and do not anticipate paying cash dividends on our common stock 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 common stock may be less valuable because a return on your investment will only occur if our common stock price appreciates and you then sell our common stock.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended June 30, 2023, none of our directors or “officers” (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of SEC Regulation S-K.

On August 6, 2023, we entered into an amended and restated change in control and severance agreement with each of Erica J. Rogers, our President and Chief Executive Officer; Lucas W. Buchanan, our Chief Financial Officer and Chief Operating Officer; and Andrew S. Davis, our Chief Commercial Officer, in each case effective as of June 22, 2022, to simplify and standardize the severance provisions amongst our executive officers. The amendments reflected therein provide for a lump sum cash payment equal to 12 months base salary for each of Messrs. Buchanan and Davis and 18 months for Ms. Rogers, plus reimbursement of premiums to maintain group health insurance continuation benefits pursuant to “COBRA” for the executive and the executive’s dependents for up to 12 months for each of Messrs. Buchanan and Davis and up to 18 months for Ms. Rogers, in the event of a termination of the executive’s employment by us without “cause” (as defined therein), excluding by reason of the executive’s death or “disability” (as defined therein), outside of the change in control protection period as provided therein. The amendments reflected therein also provide for similar payments, although 24 months base salary for Ms. Rogers, in the event of such a termination within the change in control protection period, plus an additional lump sum cash payment equal to 100% for each of Messrs. Buchanan and Davis and 200% for Ms. Rogers of the executive’s target bonus for the fiscal year of termination. All other terms and conditions of the amended and restated change in control and severance agreements remain in full force and effect.

The foregoing description of the material amendments reflected in the amended and restated change in control and severance agreements does not purport to be complete and is subject to and qualified in its entirety by reference to the full text of the amended and restated change in control and severance agreements, which are filed as Exhibits 10.4, 10.5 and 10.6 to this Quarterly Report on Form 10-Q and incorporated by reference herein.

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.

Exhibit Number	Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date
3.1**	Amended and Restated Certificate of Incorporation of Silk Road Medical, Inc..	8-K	001-38847	3.1	4/8/2019
3.2**	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Silk Road Medical, Inc.	8-K	001-38847	3.1	6/22/2021
3.3**	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Silk Road Medical, Inc.	8-K	001-38847	3.1	6/23/2023
3.4**	Amended and Restated Bylaws of Silk Road Medical, Inc.	8-K	001-38847	3.1	3/15/2023
4.1**	Specimen Common Stock Certificate of Silk Road Medical, Inc.	S-1	333-230044	4.1	8/6/2019
4.2**	Amended and Restated Stockholders Agreement dated July 7, 2017 among Silk Road Medical, Inc. and certain stockholders.	S-1	333-230044	4.3	8/6/2019
10.1**	Second Amendment to Lease dated as of May 3, 2023 between Hanover Properties, Ltd. and Silk Road Medical, Inc.	10-Q	001-38847	10.2	5/9/2023
10.2**†	First Amendment to License Agreement dated as of May 8, 2023 between Cordis US Corp., as successor to Cordis Corporation, and Silk Road Medical, Inc.	10-Q	001-38847	10.3	5/9/2023
10.3**†	Fifth Amendment to Supply Agreement dated as of May 8, 2023 between Cordis US Corp., as successor to Cordis Corporation, and Silk Road Medical, Inc.	10-Q	001-38847	10.4	5/9/2023
10.4*	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Erica Rogers.				
10.5*	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Lucas Buchanan.				
10.6*	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Andrew Davis.				
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.				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

* Filed herewith.
** Previously filed.
† Portions of this exhibit have been omitted pursuant to Rule 601(b)(10)(iv) of Regulation S-K.
\# This certification is not deemed filed with the SEC 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 this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	SILK ROAD MEDICAL, INC.
August 8, 2023	By: /s/ Erica J. Rogers Erica J. Rogers *President, Chief Executive Officer and Director* *(principal executive officer)*
August 8, 2023	By: /s/ Lucas W. Buchanan Lucas W. Buchanan *Chief Financial Officer and Chief Operating Officer* *(principal financial officer)*
August 8, 2023	By: /s/ Mhairi L. Jones Mhairi L. Jones *Chief Accounting Officer and Vice President, Finance* *(principal accounting officer)*

SILK ROAD MEDICAL, INC.

AMENDED AND RESTATED CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Amended and Restated Change in Control and Severance Agreement (the “**Agreement**”) is made between Silk Road Medical, Inc. (the “**Company**”) and Erica Rogers (the “**Executive**”), effective as of June 22, 2022.

This Agreement amends and restates that certain Change in Control and Severance Agreement effective as of March 21, 2019 (the “**Initial Effective Date**”) between the Company and the Executive and provides certain protections to the Executive in connection with a change in control of the Company or in connection with the involuntary termination of the Executive’s employment under the circumstances described in this Agreement.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will have an initial term of three (3) years commencing on the Initial Effective Date (the “**Initial Term**”). On the third (3rd) anniversary of the Initial Effective Date, this Agreement will renew automatically for additional, one (1) year terms (each, an “**Additional Term**”) unless either party provides the other party with written notice of nonrenewal at least one (1) year prior to the date of automatic renewal. Notwithstanding the foregoing, if a Change in Control occurs (a) when there are fewer than twelve (12) months remaining during the Initial Term or (b) during an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the date of the Change in Control. If the Executive becomes entitled to the benefits under Section 3 of this Agreement, then the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive’s employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to eighteen (18) months of the Executive’s Salary (as defined below), less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive’s eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company’s active employees (the “**COBRA Coverage**”), until the earliest of (A) a period of eighteen (18) months from the date of the Executive’s termination of employment, (B) the date upon which the Executive (and the Executive’s eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment, less applicable withholdings, equal to twenty-four (24) months of the Executive's Salary (such number of months, the "**Severance Period**").

(ii) Bonus Severance. A single, lump sum payment, less applicable withholdings, equal to 200% of the Executive's target annual bonus as in effect for the fiscal year in which the Qualifying CIC Termination occurs.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will provide COBRA Coverage until the earliest of (A) a period of months from the date of the Executive's termination of employment equal to the Severance Period (not to exceed eighteen (18) months), (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding Company equity awards. In the case of an equity award with performance-based vesting, unless otherwise specified in the applicable equity award agreement governing such award, all performance goals and other vesting criteria will be deemed achieved at target. For the avoidance of doubt, in the event of the Executive's Qualifying Pre-CIC Termination (as defined below), any unvested portion of the Executive's then-outstanding equity awards will remain outstanding until the earlier of (x) sixty (60) days following the Qualifying Termination or (y) the occurrence of a Change in Control, solely so that any benefits due on a Qualifying Pre-CIC Termination can be provided if a Change in Control occurs within sixty (60) days following the Qualifying Termination (provided that in no event will the Executive's stock options or similar equity awards remain outstanding beyond the equity award's maximum term to expiration). If no Change in Control occurs within sixty (60) days following a Qualifying Termination, any unvested portion of the Executive's equity awards automatically and permanently will be forfeited on the sixtieth (60^{th}) day following the date of the Qualifying Termination without having vested.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**" and that requirement, the "**Release Requirement**"), which must become effective and irrevocable no later than the 60th day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum Salary or bonus payments under Sections 3(a)(i), 3(b)(i), and 3(b)(ii) will be provided on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3(b)(iv) will be settled (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section 409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is 6 months and 1 day following the Executive's termination of employment. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means: (i) the Executive's conviction of, or plea of guilty or nolo contendere to, a felony or a crime involving moral turpitude; (ii) the Executive's admission or conviction of, or plea of guilty or nolo contendere to, an intentional act of fraud, embezzlement or theft in connection with your duties or in the course of employment with the Company Group; (iii) the Executive's intentional wrongful damage to property of the Company Group; (iv) intentional unauthorized or wrongful use or disclosure of secret processes or of proprietary or confidential information of the Company Group (or any other party to whom the Executive owes an obligation of nonuse or nondisclosure as a result of the Executive's employment relationship with the Company), including but not limited to trade secrets and customer lists; (iv) the Executive's violation of any agreement not to compete with the Company Group or to solicit either its customers or employees on behalf of competitors while remaining employed with the Company Group; (v) the Executive's intentional violation of any policy or policies regarding ethical conduct; (vi) an act of dishonesty made by the Executive in connection with the Executive's responsibilities as an employee which materially harms the Company Group, or (vii) the Executive's intentional or continued failure to perform the Executive's duties with the Company Group, as determined in good faith by the Company after being provided with notice of such failure, such notice specifying in reasonable detail the tasks which must be accomplished and a timeline for the accomplishment to avoid termination for Cause, and an opportunity to cure within thirty (30) days of receipt of such notice.

(c) "**Change in Control**" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, (A) the acquisition of additional stock by any one Person, who is considered to own more than 50% of the total voting power of the stock of the Company will not be considered a Change in Control, and (B) if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, the direct or indirect beneficial ownership of 50% or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event will not be considered a Change in Control under this subsection (i). For this purpose, indirect beneficial ownership will include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any 12 month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, 50% or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, 50% or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least 50% of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended.

(g) "**Company Group**" means the Company and its subsidiaries.

(h) “**Confidentiality Agreement**” means the At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement.

(i) “**Disability**” means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) “**Good Reason**” means the termination of the Executive’s employment with the Company Group by the Executive in accordance with the next sentence after the occurrence of one or more of the following events without the Executive’s express written consent: (i) a material reduction of the Executive’s duties, authorities, or responsibilities relative to the Executive’s duties, authorities, or responsibilities in effect immediately prior to the reduction; provided, however, that continued employment following a Change in Control with substantially the same duties, authorities, or responsibilities with respect to the Company Group’s business and operations will not constitute “Good Reason” (for example, “Good Reason” does not exist if the Executive is employed by the Company Group or a successor with substantially the same duties, authorities, or responsibilities with respect to the Company Group’s business that the Executive had immediately prior to the Change in Control regardless of whether the Executive’s title is revised to reflect the Executive’s placement within the overall corporate hierarchy or whether the Executive provides services to a subsidiary, affiliate, business unit or otherwise); (ii) a reduction by a Company Group member in the Executive’s rate of annual base salary by more than 10%; provided, however, that, a reduction of annual base salary that also applies to substantially all other similarly situated employees of the Company Group members will not constitute “Good Reason”; (iii) a material change in the geographic location of the Executive’s primary work facility or location by more than 35 miles from the Executive’s then present location; provided, that a relocation to a location that is within 35 miles from the Executive’s then-present primary residence will not be considered a material change in geographic location, or (iv) failure of a successor corporation to assume the obligations under this Agreement as contemplated by Section 8. In order for the termination of the Executive’s employment with a Company Group member to be for Good Reason, the Executive must not terminate employment without first providing written notice to the Company of the acts or omissions constituting the grounds for “Good Reason” within 60 days of the initial existence of the grounds for “Good Reason” and a cure period of 30 days following the date of written notice (the “**Cure Period**”), the grounds must not have been cured during that time, and the Executive must terminate the Executive’s employment within 30 days following the Cure Period.

(k) “**Qualifying Pre-CIC Termination**” means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) “**Qualifying Termination**” means a termination of the Executive’s employment either (i) by a Company Group member without Cause (excluding by reason of Executive’s death or Disability) or (ii) by the Executive for Good Reason, in either case, during the Change in Control Period (a “**Qualifying CIC Termination**”) or outside of the Change in Control Period (a “**Qualifying Non-CIC Termination**”).

(m) “**Salary**” means the Executive’s annual base salary as in effect immediately prior to the Executive’s Qualifying Termination (or if the termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive’s annual base salary in effect immediately prior to the reduction) or, if the Executive’s Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) 24 hours after confirmed facsimile transmission, (iv) 1 business day after deposit with a recognized overnight courier, or (v) 3 business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Silk Road Medical, Inc.
1213 Innsbruck Drive
Sunnyvale, CA 94089

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the later of (i) the giving of the notice or (ii) the end of any applicable cure period).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Choice of Law. This Agreement will be governed by the laws of the State of California without regard to California's conflicts of law rules that may result in the application of the laws of any jurisdiction other than California. To the extent that any lawsuit is permitted under this Agreement, Employee hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in California for any lawsuit filed against the Executive by the Company.

(f) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(g) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(h) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows.]

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY	SILK ROAD MEDICAL, INC.
	By: /s/ Alison Highlander
	Title: Vice President, HR
	Date: Aug 6, 2023
EXECUTIVE	/s/ Erica Rogers
	Erica Rogers
	Date: Aug 4, 2023

SILK ROAD MEDICAL, INC.

AMENDED AND RESTATED CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Amended and Restated Change in Control and Severance Agreement (the "**Agreement**") is made between Silk Road Medical, Inc. (the "**Company**") and Lucas Buchanan (the "**Executive**"), effective as of June 22, 2022.

This Agreement amends and restates that certain Change in Control and Severance Agreement effective as of March 21, 2019 (the "**Initial Effective Date**") between the Company and the Executive and provides certain protections to the Executive in connection with a change in control of the Company or in connection with the involuntary termination of the Executive's employment under the circumstances described in this Agreement.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will have an initial term of three (3) years commencing on the Initial Effective Date (the "**Initial Term**"). On the third (3rd) anniversary of the Initial Effective Date, this Agreement will renew automatically for additional, one (1) year terms (each, an "**Additional Term**") unless either party provides the other party with written notice of nonrenewal at least one (1) year prior to the date of automatic renewal. Notwithstanding the foregoing, if a Change in Control occurs (a) when there are fewer than twelve (12) months remaining during the Initial Term or (b) during an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the date of the Change in Control. If the Executive becomes entitled to the benefits under Section 3 of this Agreement, then the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive's employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to twelve (12) months of the Executive's Salary (as defined below), less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**"), until the earliest of (A) a period of twelve (12) months from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under

COBRA.

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment, less applicable withholdings, equal to twelve (12) months of the Executive's Salary (such number of months, the "**Severance Period**").

(ii) Bonus Severance. A single, lump sum payment, less applicable withholdings, equal to 100% of the Executive's target annual bonus as in effect for the fiscal year in which the Qualifying CIC Termination occurs.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will provide COBRA Coverage until the earliest of (A) a period of months from the date of the Executive's termination of employment equal to the Severance Period, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding Company equity awards. In the case of an equity award with performance-based vesting, unless otherwise specified in the applicable equity award agreement governing such award, all performance goals and other vesting criteria will be deemed achieved at target. For the avoidance of doubt, in the event of the Executive's Qualifying Pre-CIC Termination (as defined below), any unvested portion of the Executive's then-outstanding equity awards will remain outstanding until the earlier of (x) sixty (60) days following the Qualifying Termination or (y) the occurrence of a Change in Control, solely so that any benefits due on a Qualifying Pre-CIC Termination can be provided if a Change in Control occurs within sixty (60) days following the Qualifying Termination (provided that in no event will the Executive's stock options or similar equity awards remain outstanding beyond the equity award's maximum term to expiration). If no Change in Control occurs within sixty (60) days following a Qualifying Termination, any unvested portion of the Executive's equity awards automatically and permanently will be forfeited on the sixtieth (60^{th}) day following the date of the Qualifying Termination without having vested.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense

reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**" and that requirement, the "**Release Requirement**"), which must become effective and irrevocable no later than the 60th day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum Salary or bonus payments under Sections 3(a)(i), 3(b)(i), and 3(b)(ii) will be provided on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3(b)(iv) will be settled (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section

409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is 6 months and 1 day following the Executive's termination of employment. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means: (i) the Executive's conviction of, or plea of guilty or nolo contendere to, a felony or a crime involving moral turpitude; (ii) the Executive's admission or conviction of, or plea of guilty or nolo contendere to, an intentional act of fraud, embezzlement or theft in connection with your duties or in the course of employment with the Company Group; (iii) the Executive's intentional wrongful damage to property of the Company Group; (iv) intentional unauthorized or wrongful use or disclosure of secret processes or of proprietary or confidential information of the Company Group (or any other party to whom the Executive owes an obligation of nonuse or nondisclosure as a result of the Executive's employment relationship with the Company), including but not limited to trade secrets and customer lists; (iv) the Executive's violation of any agreement not to compete with the Company Group or to solicit either its customers or employees on behalf of competitors while remaining employed with the Company Group; (v) the Executive's intentional violation of any policy or policies regarding ethical conduct; (vi) an act of dishonesty made by the Executive in connection with the Executive's responsibilities as an employee which materially harms the Company Group, or (vii) the Executive's intentional or continued failure to perform the Executive's duties with the Company Group, as determined in good faith by the Company after being provided with notice of such failure, such notice specifying in reasonable detail the tasks which must be accomplished and a timeline for the accomplishment to avoid termination for Cause, and an opportunity to cure within thirty (30) days of receipt of such notice.

(c) "**Change in Control**" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, (A) the acquisition of additional stock by any one Person, who is considered to own more than 50% of the total voting power of the stock of the Company will not be considered a Change in Control, and (B) if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, the direct or indirect beneficial ownership of 50% or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event will not be considered a Change in Control under this subsection (i). For this purpose, indirect beneficial ownership will include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any 12 month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, 50% or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, 50% or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least 50% of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended.

(g) "**Company Group**" means the Company and its subsidiaries.

(h) "**Confidentiality Agreement**" means the At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement.

(i) "**Disability**" means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) "**Good Reason**" means the termination of the Executive's employment with the Company Group by the Executive in accordance with the next sentence after the occurrence of one or more of the following events without the Executive's express written consent: (i) a material reduction of the Executive's duties, authorities, or responsibilities relative to the Executive's duties, authorities, or responsibilities in effect immediately prior to the reduction; provided, however, that continued employment following a Change in Control with substantially the same duties, authorities, or responsibilities with respect to the Company Group's business and operations will not constitute "Good Reason" (for example, "Good Reason" does not exist if the Executive is employed by the Company Group or a successor with substantially the same duties, authorities, or responsibilities with respect to the Company Group's business that the Executive had immediately prior to the Change in Control regardless of whether the Executive's title is revised to reflect the Executive's placement within the overall corporate hierarchy or whether the Executive provides services to a subsidiary, affiliate, business unit or otherwise); (ii) a reduction by a Company Group member in the Executive's rate of annual base salary by more than 10%; provided, however, that, a reduction of annual base salary that also applies to substantially all other similarly situated employees of the Company Group members will not constitute "Good Reason"; (iii) a material change in the geographic location of the Executive's primary work facility or location by more than 35 miles from the Executive's then present location; provided, that a relocation to a location that is within 35 miles from the Executive's then-present primary residence will not be considered a material change in geographic location, or (iv) failure of a successor corporation to assume the obligations under this Agreement as contemplated by Section 8. In order for the termination of the Executive's employment with a Company Group member to be for Good Reason, the Executive must not terminate employment without first providing written notice to the Company of the acts or omissions constituting the grounds for "Good Reason" within 60 days of the initial existence of the grounds for "Good Reason" and a cure period of 30 days following the date of written notice (the "**Cure Period**"), the grounds must not have been cured during that time, and the Executive must terminate the Executive's employment within 30 days following the Cure Period.

(k) "**Qualifying Pre-CIC Termination**" means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) "**Qualifying Termination**" means (i) a termination of the Executive's employment by a Company Group member without Cause (excluding by reason of Executive's death or Disability) outside of the Change in Control Period (a "**Qualifying Non-CIC Termination**") or (ii) a termination of the Executive's employment (A) by a Company Group member without Cause (excluding by reason of Executive's death or Disability) or (B) by the Executive for Good Reason, in either (A) or (B) during the Change in Control Period (a "**Qualifying CIC Termination**").

(m) "**Salary**" means the Executive's annual base salary as in effect immediately prior to the Executive's Qualifying Termination (or if the termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive's annual base salary in effect immediately prior to the reduction) or, if the Executive's Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) 24 hours after confirmed facsimile transmission, (iv) 1 business day after deposit with a recognized overnight courier, or (v) 3 business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Silk Road Medical, Inc.
1213 Innsbruck Drive
Sunnyvale, CA 94089

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the later of (i) the giving of the notice or (ii) the end of any applicable cure period).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation

from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Choice of Law. This Agreement will be governed by the laws of the State of California without regard to California's conflicts of law rules that may result in the application of the laws of any jurisdiction other than California. To the extent that any lawsuit is permitted under this Agreement, Employee hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in California for any lawsuit filed against the Executive by the Company.

(f) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(g) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(h) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows.]

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY	SILK ROAD MEDICAL, INC.
	By: /s/ Alison Highlander
	Title: Vice President, HR
	Date: Aug 6, 2023
EXECUTIVE	/s/ Lucas Buchanan
	Lucas Buchanan
	Date: Aug 4, 2023

SILK ROAD MEDICAL, INC.

AMENDED AND RESTATED CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Amended and Restated Change in Control and Severance Agreement (the "**Agreement**") is made between Silk Road Medical, Inc. (the "**Company**") and Andrew Davis (the "**Executive**"), effective as of June 22, 2022.

This Agreement amends and restates that certain Change in Control and Severance Agreement effective as of March 21, 2019 (the "**Initial Effective Date**") between the Company and the Executive and provides certain protections to the Executive in connection with a change in control of the Company or in connection with the involuntary termination of the Executive's employment under the circumstances described in this Agreement.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will have an initial term of three (3) years commencing on the Initial Effective Date (the "**Initial Term**"). On the third (3rd) anniversary of the Initial Effective Date, this Agreement will renew automatically for additional, one (1) year terms (each, an "**Additional Term**") unless either party provides the other party with written notice of nonrenewal at least one (1) year prior to the date of automatic renewal. Notwithstanding the foregoing, if a Change in Control occurs (a) when there are fewer than twelve (12) months remaining during the Initial Term or (b) during an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the date of the Change in Control. If the Executive becomes entitled to the benefits under Section 3 of this Agreement, then the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive's employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to twelve (12) months of the Executive's Salary (as defined below), less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**"), until the earliest of (A) a period of twelve (12) months from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under

COBRA.

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment, less applicable withholdings, equal to twelve (12) months of the Executive's Salary (such number of months, the "**Severance Period**").

(ii) Bonus Severance. A single, lump sum payment, less applicable withholdings, equal to 100% of the Executive's target annual bonus as in effect for the fiscal year in which the Qualifying CIC Termination occurs.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will provide COBRA Coverage until the earliest of (A) a period of months from the date of the Executive's termination of employment equal to the Severance Period, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding Company equity awards. In the case of an equity award with performance-based vesting, unless otherwise specified in the applicable equity award agreement governing such award, all performance goals and other vesting criteria will be deemed achieved at target. For the avoidance of doubt, in the event of the Executive's Qualifying Pre-CIC Termination (as defined below), any unvested portion of the Executive's then-outstanding equity awards will remain outstanding until the earlier of (x) sixty (60) days following the Qualifying Termination or (y) the occurrence of a Change in Control, solely so that any benefits due on a Qualifying Pre-CIC Termination can be provided if a Change in Control occurs within sixty (60) days following the Qualifying Termination (provided that in no event will the Executive's stock options or similar equity awards remain outstanding beyond the equity award's maximum term to expiration). If no Change in Control occurs within sixty (60) days following a Qualifying Termination, any unvested portion of the Executive's equity awards automatically and permanently will be forfeited on the sixtieth (60^{th}) day following the date of the Qualifying Termination without having vested.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense

reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**" and that requirement, the "**Release Requirement**"), which must become effective and irrevocable no later than the 60th day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum Salary or bonus payments under Sections 3(a)(i), 3(b)(i), and 3(b)(ii) will be provided on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3(b)(iv) will be settled (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section

409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is 6 months and 1 day following the Executive's termination of employment. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means: (i) the Executive's conviction of, or plea of guilty or nolo contendere to, a felony or a crime involving moral turpitude; (ii) the Executive's admission or conviction of, or plea of guilty or nolo contendere to, an intentional act of fraud, embezzlement or theft in connection with your duties or in the course of employment with the Company Group; (iii) the Executive's intentional wrongful damage to property of the Company Group; (iv) intentional unauthorized or wrongful use or disclosure of secret processes or of proprietary or confidential information of the Company Group (or any other party to whom the Executive owes an obligation of nonuse or nondisclosure as a result of the Executive's employment relationship with the Company), including but not limited to trade secrets and customer lists; (iv) the Executive's violation of any agreement not to compete with the Company Group or to solicit either its customers or employees on behalf of competitors while remaining employed with the Company Group; (v) the Executive's intentional violation of any policy or policies regarding ethical conduct; (vi) an act of dishonesty made by the Executive in connection with the Executive's responsibilities as an employee which materially harms the Company Group, or (vii) the Executive's intentional or continued failure to perform the Executive's duties with the Company Group, as determined in good faith by the Company after being provided with notice of such failure, such notice specifying in reasonable detail the tasks which must be accomplished and a timeline for the accomplishment to avoid termination for Cause, and an opportunity to cure within thirty (30) days of receipt of such notice.

(c) "**Change in Control**" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, (A) the acquisition of additional stock by any one Person, who is considered to own more than 50% of the total voting power of the stock of the Company will not be considered a Change in Control, and (B) if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, the direct or indirect beneficial ownership of 50% or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event will not be considered a Change in Control under this subsection (i). For this purpose, indirect beneficial ownership will include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any 12 month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, 50% or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, 50% or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least 50% of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) “**COBRA**” means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) “**Code**” means the Internal Revenue Code of 1986, as amended.

(g) “**Company Group**” means the Company and its subsidiaries.

(h) “**Confidentiality Agreement**” means the At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement.

(i) “**Disability**” means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) “**Good Reason**” means the termination of the Executive’s employment with the Company Group by the Executive in accordance with the next sentence after the occurrence of one or more of the following events without the Executive’s express written consent: (i) a material reduction of the Executive’s duties, authorities, or responsibilities relative to the Executive’s duties, authorities, or responsibilities in effect immediately prior to the reduction; provided, however, that continued employment following a Change in Control with substantially the same duties, authorities, or responsibilities with respect to the Company Group’s business and operations will not constitute “Good Reason” (for example, “Good Reason” does not exist if the Executive is employed by the Company Group or a successor with substantially the same duties, authorities, or responsibilities with respect to the Company Group’s business that the Executive had immediately prior to the Change in Control regardless of whether the Executive’s title is revised to reflect the Executive’s placement within the overall corporate hierarchy or whether the Executive provides services to a subsidiary, affiliate, business unit or otherwise); (ii) a reduction by a Company Group member in the Executive’s rate of annual base salary by more than 10%; provided, however, that, a reduction of annual base salary that also applies to substantially all other similarly situated employees of the Company Group members will not constitute “Good Reason”; (iii) a material change in the geographic location of the Executive’s primary work facility or location by more than 35 miles from the Executive’s then present location; provided, that a relocation to a location that is within 35 miles from the Executive’s then-present primary residence will not be considered a material change in geographic location, or (iv) failure of a successor corporation to assume the obligations under this Agreement as contemplated by Section 8. In order for the termination of the Executive’s employment with a Company Group member to be for Good Reason, the Executive must not terminate employment without first providing written notice to the Company of the acts or omissions constituting the grounds for “Good Reason” within 60 days of the initial existence of the grounds for “Good Reason” and a cure period of 30 days following the date of written notice (the “**Cure Period**”), the grounds must not have been cured during that time, and the Executive must terminate the Executive’s employment within 30 days following the Cure Period.

(k) “**Qualifying Pre-CIC Termination**” means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) “**Qualifying Termination**” means (i) a termination of the Executive’s employment by a Company Group member without Cause (excluding by reason of Executive’s death or Disability) outside of the Change in Control Period (a “**Qualifying Non-CIC Termination**”) or (ii) a termination of the Executive's employment (A) by a Company Group member without Cause (excluding by reason of Executive's death or Disability) or (B) by the Executive for Good Reason, in either (A) or (B) during the Change in Control Period (a "**Qualifying CIC Termination**").

(m) "**Salary**" means the Executive's annual base salary as in effect immediately prior to the Executive's Qualifying Termination (or if the termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive's annual base salary in effect immediately prior to the reduction) or, if the Executive's Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) 24 hours after confirmed facsimile transmission, (iv) 1 business day after deposit with a recognized overnight courier, or (v) 3 business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Silk Road Medical, Inc.
1213 Innsbruck Drive
Sunnyvale, CA 94089

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the later of (i) the giving of the notice or (ii) the end of any applicable cure period).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation

from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Choice of Law. This Agreement will be governed by the laws of the State of California without regard to California's conflicts of law rules that may result in the application of the laws of any jurisdiction other than California. To the extent that any lawsuit is permitted under this Agreement, Employee hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in California for any lawsuit filed against the Executive by the Company.

(f) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(g) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(h) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows.]

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY	SILK ROAD MEDICAL, INC.
	By: /s/ Alison Highlander
	Title: Vice President, HR
	Date: Aug 6, 2023
EXECUTIVE	/s/ Andrew Davis
	Andrew Davis
	Date: Aug 6, 2023

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. 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 8, 2023

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. 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 and Chief Operating Officer
(Principal Financial Officer)

Date: August 8, 2023

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, 2023, 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 and Chief Operating Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), that:

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 8, 2023

/s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

Date: August 8, 2023

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.