Silk Road Medical, Inc.
2023 Annual Report

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023
OR

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

For transition period from to
Commission File Number 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

1213 Innsbruck Dr. Sunnyvale, CA 94089
(Address of registrant's 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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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) Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $1.2 billion as of June 30, 2023 based on the closing sale price of the registrant's common stock on the Nasdaq Global Select Market on such date. Solely for purposes of this disclosure, shares of common stock held by executive officers and directors of the registrant as of such date have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 23, 2024, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 39,174,619.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2024 Annual Meeting of Stockholders, or the 2024 Proxy Statement, are incorporated by reference into Part III of this report where indicated. The 2024 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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, prospects, 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,” “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 2024 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 approvals and 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 manage our recent Chief Executive Officer transition and retain and recruit key personnel, including the continued expansion of our sales and marketing infrastructure, and the anticipated timing and effect of such actions;
- our ability to obtain an adequate supply of materials, components and finished goods 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 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K.

These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to 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 Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the SEC as exhibits to this Annual Report on Form 10-K 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

Item 1. Business

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. Our business is focused on 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.

TCAR relies on two novel concepts - minimally-invasive direct carotid access in the neck and high-rate blood flow reversal during the procedure to protect the brain - and combines novel endovascular techniques with fundamental surgical principles. TCAR using our portfolio of products has been clinically demonstrated to reduce the upfront morbidity and mortality risks commonly associated with carotid endarterectomy while maintaining a reduction in long-term stroke risk. We have obtained U.S. Food and Drug Administration, or FDA, approvals, secured specific Medicare reimbursement coverage, and commercialize products engineered and indicated specifically for transcarotid use, in patients who require carotid revascularization and who meet certain treatment criteria. In the second quarter of 2022, we announced FDA label and Medicare coverage expansions for the use of TCAR in standard surgical risk patients in the TCAR Surveillance Project, or TSP. Effective October 11, 2023, the U.S. Centers for Medicare and Medicaid Services, or CMS, published the final decision memo for National Coverage Determination, or NCD, 20.7 expanding coverage for CAS, including TCAR, under indication B4 for both high risk and standard surgical risk patients. TCAR remains covered within the TSP as well as outside of the TSP under the revised NCD 20.7. As of December 31, 2023, more than 85,000 TCAR procedures have been performed globally, including more than 25,000 in the United States during 2023.

Carotid artery disease is the progressive buildup of plaque causing narrowing of the arteries in the front of the neck, which supply blood flow to the brain. Plaque can embolize, or break away from the arterial wall, and travel toward the brain and interrupt critical blood supply, leading to an ischemic stroke. Carotid artery disease is one of the leading causes of stroke, and stroke is one of the most catastrophic, debilitating, and costly conditions worldwide. We believe the best way to mitigate the mortality, morbidity and cost burden of stroke is to prevent strokes in the first place. Clinical evidence has demonstrated that with proper diagnosis and treatment, stroke due to carotid artery disease is mostly preventable. We believe there were approximately 4.4 million people with carotid artery disease in the United States in 2022, with an estimated 440,000 diagnoses in 2022, and existing treatment options have substantial safety and effectiveness limitations.

The main goal of treating carotid artery disease is to prevent a future stroke. Unfortunately, one of the main complications of existing treatments for carotid artery disease is causing a stroke, along with other procedure-related adverse events. When intervention beyond medical management is warranted, the current standard of care for reduction in stroke risk is an invasive carotid revascularization procedure called carotid endarterectomy, or CEA. To perform a CEA, a physician makes a large incision in the neck, cuts the carotid artery open, and then removes the plaque from inside the vessel. CEA was first performed in 1953, and while generally effective at reducing stroke risk in the long term, large randomized clinical trials have demonstrated that CEA is associated with a significant risk of adverse events, including cranial nerve injury, heart attack, wound complications, and, in some cases, even stroke and death. These risks are elevated in certain patient populations.

To address the invasiveness of CEA, transfemoral carotid artery stenting, or CAS, was developed in the 1990s. The CAS procedure uses minimally-invasive catheters traveling from a puncture site in the groin to place a stent in the carotid artery in the neck to restrain the plaque and prevent embolization that could cause a stroke. While both CEA and CAS have been clinically demonstrated to reduce long-term stroke risk, randomized clinical trials and other studies have shown that CAS, relative to CEA, often results in an almost two-fold increase in stroke within 30 days following treatment, which we believe is due to inadequate protection of the brain. Accordingly, to date, CEA has remained the standard of care. Therefore, we believe reducing the rate of morbidity and mortality of CEA is an unmet clinical need that continues to persist.

TCAR is a minimally-invasive procedure intended to address the morbidity of CEA and the 30-day stroke risk of CAS while maintaining a reduction in long-term stroke risk beyond the first 30 days. TCAR starts with a small incision in the neck slightly above the collarbone, otherwise known as transcarotid access, through which our ENROUTE® Transcarotid Stent System, or ENROUTE stent, is placed during a period of temporary high-rate blood flow reversal that is enabled by our ENROUTE® Transcarotid Neuroprotection System, or ENROUTE NPS. Blood flow reversal directs embolic debris that could cause a stroke away from the brain, while the stent braces the plaque and prevents embolization to afford a reduction in long-term stoke risk. We believe that by meeting the standard of brain protection and reduction in 30-day and

long-term stroke risk afforded by CEA, while providing benefits commensurate with an endovascular, minimally-invasive approach, TCAR could become the preferred alternative for carotid revascularization. Additionally, we believe that as our technology becomes more widely adopted, TCAR may become a compelling alternative for patients who are treated with medical management alone each year.

Based on the estimated 440,000 new carotid artery disease diagnoses that occurred in the United States in 2022, we believe a total annual U.S. market opportunity of approximately $3.1 billion exists for our portfolio of TCAR products. We estimate that there were approximately 172,000 carotid revascularization procedures performed in 2022, which we estimate to represent a market conversion opportunity of approximately $1.2 billion. More than 25,000 TCAR procedures were performed in 2023 in the United States using our products, representing approximately 5.7% of annual diagnoses of carotid artery disease.

The safety, effectiveness and clinical advantages of TCAR have been demonstrated in multiple clinical trials, post-market studies and registries that have been published in over 300 TCAR publications to date, representing outcomes in tens of thousands of patients. The results of our U.S. pivotal trial, ROADSTER, reflect the lowest reported 30-day stroke rate for any prospective, multicenter clinical trial of carotid stenting of which we are aware. Our ROADSTER 2 post-approval study was completed in 2019 and showed a 30-day stroke rate of 0.6% in the primary analysis population. Additionally, data on real-world outcomes of TCAR relative to CEA and CAS have continued to accrue through the ongoing TCAR Surveillance Project, which is an ongoing open-ended registry sponsored by the Society for Vascular Surgery through the Vascular Quality Initiative, or VQI. In a VQI study published in the *Journal of the American Medical Association* in December 2019, a propensity matched analysis of 3,286 high surgical risk patients in each cohort showed in-hospital stroke or death was significantly lower for TCAR at 1.6% versus 3.1% for CAS, $p < 0.001$. The statistically significant difference favoring TCAR persisted through 30 days and 1 year. In a VQI study published in the *Annals of Surgery* in September 2020, a propensity matched analysis of 6,384 high surgical risk patients in each cohort demonstrated significant reduction in the risk of in-hospital myocardial infarction and cranial nerve injury after TCAR compared to CEA (0.5% vs. 0.9%, $p = 0.005$; 0.4% vs. 2.7%, $p < 0.001$, respectively), with no differences in the rates of in-hospital stroke/death (1.6% TCAR and 1.6% CEA). In a more recent analysis of both high risk and standard risk surgical risk patients, a 2022 VQI study by Zhang GQ, et al published in the *Journal of Vascular Surgery*, compared outcomes (composite of stroke, death and myocardial infarction) using a multivariate logistic regression analysis analyzing TCAR procedures using the predicate device, TF-CAS using distal filters and CEA procedures from 2015-2020. Within the high risk patient cohort of 10,903 TCAR vs. 7,967 CEA vs. 9,896 TF-CAS procedures, TCAR demonstrated significantly lower odds of 30-day stroke, death and stroke/death and myocardial infarction for TCAR compared to both CEA and TF-CAS. Within the standard risk cohort of 4,694 TCAR vs. 33,720 CEA vs. 7,351 TF-CAS procedures, TCAR and CEA showed equivalent odds of 30-day stroke, death, and stroke/death, whereas TFCAS was associated with significantly higher risk for these endpoints. In 2023, an analysis of the National Inpatient Sample database, which is the largest all-payor inpatient database for ~35 million hospitalizations nationwide, was published by Ramsay IA, et al in the journal *Operative Neurosurgery* and demonstrated the risk of stroke with TCAR was significantly lower compared to CEA.

TCAR is reimbursed based on established Current Procedural Technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid artery disease and carotid artery stenting. Our ENROUTE NPS is currently the only FDA-cleared transcarotid neuroprotection device. CMS is the primary payer for carotid revascularization procedures as carotid artery disease is most often a disease of the elderly, and we estimate Medicare covers approximately 75% of patients treated.

We began commercializing our products in the United States in late 2015. Our revenue increased to $177.1 million for the year ended December 31, 2023 compared to $138.6 million for the year ended December 31, 2022, representing growth of 28%. Our net losses were $55.7 million and $55.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, our accumulated deficit was $399.5 million and $343.7 million, respectively.

Our Product Portfolio

TCAR is enabled by our proprietary portfolio of TCAR products designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. In addition to enabling the safety and effectiveness of TCAR, our proprietary products are specifically designed to enable a short learning curve, consistent ease of use and physician comfort. Our products are also currently the only devices cleared and approved by the FDA specifically for transcarotid use.

Our current product portfolio consists of the following five single-use components:

ENROUTE Transcarotid Neuroprotection System		• Used to directly access the common carotid artery and establish temporary blood flow reversal • Embolic debris is captured and filtered, returning filtered blood to the femoral vein • Allows for flow modulation enabling lesion imaging and patient tolerability • Only FDA-cleared transcarotid neuroprotection system
ENROUTE Transcarotid Stent System		• Cylindrical and tapered configurations with optimized cell design and auto-conforming technology • Designed for transcarotid access, improving the accuracy and ergonomics of the TCAR procedure • Only FDA-approved transcarotid stent system optimized for the TCAR procedure
ENHANCE Transcarotid Peripheral Access Kit		• Used to gain initial access to the common carotid artery • Only access kit specifically designed for use in the common carotid artery
ENROUTE 0.014" Guidewire		• Designed for precise and atraumatic vessel navigation and target lesion crossing for delivery of interventional devices • Short working length and proprietary tip designed for the TCAR procedure
ENROUTE Enflate Transcarotid RX Balloon Dilation Catheter		• Only transcarotid rapid exchange balloon on the market and only specialty balloon designed for the TCAR procedure • Short working length for transcarotid access and sizes optimized for use with the ENROUTE stent system • Highly visible radiopaque markers for accurate positioning

In the second quarter of 2023, we received 510(K) clearance for our next generation neuroprotection system, or ENROUTE NPS PLUS, which is designed to support additional ease-of-use and further minimize the risk for complications. We are planning for the upcoming launch of our ENROUTE NPS PLUS in the first half of 2024. We also received PMA approval for tapered configurations of our ENROUTE stent in the second quarter of 2023, which will provide greater choice for physicians to address the diversity of patient specific anatomy. We initiated a limited market release in the first quarter of 2024 with a full market release planned in the first half of 2024.

Clinical Data

The safety, effectiveness and clinical advantages of TCAR have been demonstrated in multiple clinical trials, post-market studies and registries that have been published in over 300 TCAR publications to date. Our first-in-human trial, the PROOF Study, was initiated as a feasibility study to assess the safety and performance of the ENROUTE NPS and later was expanded to support CE marking of the ENROUTE NPS. Data from the PROOF Study were also used to support FDA approval of the investigational device exemption, or IDE, for the ROADSTER Study. Data from the pivotal cohort of the ROADSTER Study supported FDA 510(k) clearance of the ENROUTE NPS, and a subset of the data supported pre-market, or PMA, approval of the ENROUTE stent. We have completed a post-market approval study, ROADSTER 2, which was designed to evaluate the outcomes in TCAR procedures using the ENROUTE stent used in conjunction with the ENROUTE NPS in broader, "real-world" use among 692 patients that were enrolled. In May 2022, FDA granted approval for an expanded label indication of the ENROUTE stent allowing for treatment of patients at standard surgical risk, in addition to patients at high surgical risk. This approval was obtained by submitting a retrospective matched analysis of 5,066 standard risk TCAR patients with 15,198 CEA patients in a 1:3 ratio from VQI's TCAR Surveillance Project and CEA registries, both sponsored by the Society for Vascular Surgery. Data on TCAR outcomes also continues to accrue through TSP, an ongoing real-world, open-ended registry. The VQI stated that > 60,000 TCAR procedures have been submitted to the registry as of December 31, 2023.

Summary of Key Clinical Trials

	Clinical Trials				
	PROOF	**ROADSTER**	**ROADSTER 2**	**ROADSTER 3**	**TCAR Surveillance Project**
Study Type	First in Human CE Marking DW-MRI Sub-Study	U.S. Pivotal IDE Study	U.S. Post-Approval Study	U.S. Post-Approval Study	Real world observation
Patients	75 pivotal 56 DW-MRI Sub-Study	67 Lead-in 141 Pivotal 78 Continued Access 52 Stent Sub-Study	692	Up to 400 with a minimum of 315 per protocol patients	Open Ended
Profile	High Surgical Risk and Standard Surgical Risk	High Surgical Risk	High Surgical Risk	Standard Surgical Risk	High Surgical Risk and Standard Surgical Risk
Status	Complete	Complete	Complete	Enrolling	Ongoing - > 60,000 TCAR cases as of December 31, 2023, per VQI
Carotid Stent Systems Used	CE Marked Carotid Stents, including the Cordis Precise Stent	FDA Approved Carotid Stents, including the Cordis Precise Stent	ENROUTE Transcarotid Stent System	ENROUTE Transcarotid Stent System	ENROUTE Transcarotid Stent System

Summary of TCAR Clinical Trial Outcomes

	PROOF	**Pooled ROADSTER**		**ROADSTER 2**	
	Intention to Treat Population	**Intention to Treat Population**	**Per-protocol**	**Intention to Treat Population**	**Per-protocol**
Stroke at 30 days					
All stroke	1.3 %	1.4 %	0.5 %	1.9 %	0.6 %
All stroke and death	1.3 %	2.3 %	1.5 %	2.3 %	0.8 %
Other adverse events at 30 days					
Myocardial infarction	0.0 %	1.4 %	1.0 %	0.9 %	0.9 %
Cranial nerve injury*	2.7 %	0.5 %	NR	1.40 %	NR
(Acute)					
Cranial nerve injury	2.7 %	0.0 %	NR	0.9 %**	NR
(persisting at 6 months)					
Procedural information					
Mean procedure time (mins)	NR	73.2	NR	74.8	74.6
Mean length of stay *(days)*	NR	1.7	NR	NR	1.6

*Only tabulated for Intention to Treat Population.
**Evaluated at 90 days.

PROOF First-in-human Clinical Trial

Our first-in-human trial, the PROOF Study, was a single-arm trial conducted at one trial site in Europe from 2009 to 2012. The PROOF Study was initiated as a feasibility study to assess the safety and performance of the ENROUTE NPS in a limited number of patients, initially enrolling 10 patients. The PROOF Study was later expanded to 75 patients to collect the clinical data necessary to support the original CE marking of the ENROUTE NPS. The results from the PROOF Study demonstrated TCAR was technically feasible and resulted in a minor stroke incidence of 1.3% within 30 days (zero

major strokes), which was significantly lower than that reported for CAS in prior clinical trials. A sub-study of 56 patients who underwent pre- and post-procedure diffusion-weighted magnetic resonance image scanning, or DW-MRI, demonstrated only 18% of the sub-study population presented with ipsilateral new white lesions. This was comparable to CEA results in prior clinical trials and significantly less than that reported in prior CAS trials. Data from the PROOF Study were also used to support FDA approval of the IDE for the ROADSTER Study.

Pivotal ROADSTER Clinical Trial

Our pivotal trial, the ROADSTER Study, was a single-arm trial conducted at 17 sites across the United States and one site in Europe from 2012 to 2014. The design of the ROADSTER Study, which was used to support FDA 510(k) clearance of the ENROUTE NPS, was largely based upon predicate embolic prevention studies and followed the relevant FDA guidance published in 2008. In the pivotal phase, the ROADSTER study enrolled 141 patients that were classified as being at high surgical risk. The primary endpoint of the ROADSTER Study was a hierarchical composite of stroke, death or myocardial infarction within 30 days.

Among the intention-to-treat, study population, which included patients treated despite major protocol deviations, the primary endpoint event rate at 30 days was 3.5%, comprised of two strokes, two deaths, and one myocardial infarction. Of note, in the per protocol analysis, which included only patients who met all study eligibility criteria, the primary endpoint event rate was 2.9%, comprised of one stroke, two deaths, and one myocardial infarction. The data from the intention-to-treat analysis supported FDA 510(k) clearance of the ENROUTE NPS.

A continued access phase of the ROADSTER Study was conducted during the time that the 510(k) premarket notification for the ENROUTE NPS was under review by FDA. This phase enrolled an additional 78 patients with the same primary and secondary endpoints and similar results as the pivotal phase of the ROADSTER Study. The ENROUTE NPS was 510(k) cleared by the FDA in February 2015.

Following a pre-submission interaction with the FDA, the FDA permitted data from a sub-analysis of 52 patients in the ROADSTER Study who were treated with the Cordis Precise Pro RX Carotid Stent System to be used, in conjunction with existing data from Cordis on CAS clinical trials performed with the Cordis Precise Pro RX Stent System, or Precise stent, to support our pre-market approval application for the ENROUTE stent. The ENROUTE stent system and the Precise stent system share the same design for the stent implant itself, and differ only in the design of the delivery system. Based on this data, the pre-market approval application for the ENROUTE stent was approved in May 2015.

We also initiated a separate sub-study of patients treated on a PP basis in the ROADSTER pivotal and continued access cohorts to assess the longer-term rate of ipsilateral stroke beyond 30 days. This sub-analysis, which consisted of 164 patients including 112 from the pivotal phase and 52 from the continued access phase, provided insight into the ability of TCAR to limit stroke incidence in longer-term follow-up. At one-year follow-up, the ipsilateral stroke rate was 0.6% beyond 30 days.

ROADSTER 2 U.S. Post-Market Approval Study

The ROADSTER 2 Post-Market Approval Study was a condition of PMA approval for the ENROUTE stent. The study evaluated the outcomes in TCAR using the ENROUTE stent in conjunction with the ENROUTE NPS in broader, “real world” use. Similar to the sub-analysis from the ROADSTER Study that led to PMA approval of the ENROUTE stent, the primary endpoint, was the rate of procedural success at 30 days in high surgical risk patients with a three-year minimum life expectancy in the PP study population.

The ROADSTER 2 study enrolled 692 patients at 42 sites, of which 632 patients were included in the PP analysis. Among the operating physicians in the study, 62% of the participating patients were treated by physicians who did not participate in the pivotal ROADSTER Study. Enrollment commenced in 2015 and was completed, along with the final 30-day follow-up assessments in 2019.

The primary endpoint of ROADSTER 2 was successfully met with a procedural success rate of 97.9%, which compared favorably to the rate of procedural success (98.1%) in the ROADSTER Sub-Study population. Data from a subset of ROADSTER 2 subjects (n=155) were analyzed to assess the incidence of ipsilateral stroke from day 31 through day 365 post-procedure. The ipsilateral stroke rate at one-year follow-up was 0% beyond 30 days.

The Society for Vascular Surgery’s TCAR Surveillance Project

The TCAR Surveillance Project was implemented in September 2016 as an initiative of the Society for Vascular Surgery Patient Safety Organization. The TCAR Surveillance Project is an ongoing, open-ended registry that was designed to monitor the safety and effectiveness of transcarotid stents placed directly into the internal carotid artery while

reversing blood flow. It is intended to compare TCAR with CEA in centers that participate in the Society for Vascular Surgery VQI. The TCAR Surveillance Project was reviewed by the FDA and deemed to be a scientifically valid extension study of TCAR, thereby allowing CMS to provide coverage within the parameters of the existing National Coverage Determination (NCD 20.7). The Society for Vascular Surgery VQI is designed to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information, and is available to all providers of vascular health care and their respective institutions participating in the registry. Because data from transfemoral CAS and CEA procedures are also collected in their respective registries within the Society for Vascular Surgery VQI, comparisons of TCAR to transfemoral CAS or CEA can also be made.

Eligible patients must meet the inclusion criteria specified for the TCAR Surveillance Project. This means patients must have had their TCAR procedure performed using any FDA-cleared transcarotid proximal embolic protection device utilizing flow reversal, such as our ENROUTE NPS, and any FDA-approved transcarotid stent, such as our ENROUTE stent**.** To date, the ENROUTE NPS is the only such device cleared and approved by the FDA. Additionally, patients had to be at high surgical risk. Following FDA's approval expanding the indication for the ENROUTE stent to standard surgical risk patients, CMS announced expanded coverage for standard risk patients entered in TSP in June 2022. As a result, TCAR procedures performed for either high surgical risk or standard surgical risk patients who are entered into TSP are eligible for reimbursement by Medicare if the patients meet the additional requirements set forth above.

The Society for Vascular Surgery VQI has reported that 778 centers have contributed more than 60,000 TCAR procedures to the CAS VQI registry as of December 31, 2023. Over time, it is expected that physicians and academic researchers will continue to query the database and produce publications in peer review journals, and present data at medical conferences, regarding the safety and effectiveness of TCAR in real world use.

In October 2023, CMS revised the NCD to cover carotid artery stenting, including TCAR, in both high and standard surgical risk patients, following a request to re-open the NCD from a group of physicians labeled the Multispecialty Carotid Alliance, or MSCA, in June 2022. In their review and as suggested by the MSCA, CMS considered evidence published from the ACT I, CREST (long-term results), SPACE-2, and ACST-2 randomized controlled trials of CAS versus CEA, amongst other datasets. In addition, CMS reviewed multiple publications supporting TCAR including the ROADSTER and ROADSTER 2 studies, and large real-world evidence, or RWE, published datasets from the TCAR Surveillance Project within the VQI, including propensity-matched comparisons to each of CEA and CAS. Under the recent NCD, TCAR remains covered within the TSP while expanding TCAR coverage outside of the TSP, which opens up the potential for some new opportunities in hospitals that previously chose not to participate in the TSP. The revised coverage determination stipulates that such procedures must include documented shared decision-making with the patient prior to treatment, independent neurological assessments, imaging requirements and the maintenance of facility and physician standards. While these requirements are new for carotid artery stenting, they do not apply to procedures done under the auspices of the TSP.

TCAR Surveillance Project: TCAR vs. CAS

In a study published in the *Journal of the American Medical Association* in December 2019, TCAR was compared to CAS in a propensity score matched analysis with 3,286 pairs. TCAR was associated with a lower risk of in-hospital stroke or death (1.6% vs 3.1%; P < .001), stroke (1.3% vs 2.4%; P = .001), and death (0.4% vs 1.0%; P = .008). As expected with two minimally invasive procedures, there was no statistically significant difference in the risk of perioperative MI between the two cohorts (0.2% for TCAR vs. 0.3% for TFCAS; P = .47). At 1 year using Kaplan-Meier life-table estimation, TCAR was associated with a lower risk of ipsilateral stroke or death (5.1% vs 9.6%; hazard ratio, 0.52 [95%CI, 0.41 to 0.66]; P < .001). TFCAS was associated with more radiation (median fluoroscopy time, 5 minutes [interquartile range {IQR}, 3 to 7] vs 16 minutes [IQR, 11 to 23]; P < .001) and more contrast usage (median contrast used, 30 mL [IQR, 20 to 45] vs 80 mL [IQR, 55 to 122]; P < .001).

TCAR Surveillance Project: TCAR vs. CEA

In a study published in the *Annals of Surgery* in September 2020, TCAR was compared to CEA in propensity score matched high surgical risk patients who underwent TCAR or CEA for carotid artery stenosis (2016-2019). Propensity scores were calculated based on baseline clinical variables and used to match patients in the two treatment groups (n=6,384 each). The primary endpoint was the combined outcome of perioperative stroke and/or death. No significant differences were observed between TCAR and CEA in terms of in-hospital stroke/death [TCAR,1.6% vs. CEA,1.6%, P=.945], stroke [1.4% vs. 1.4%, P=.881], or death [0.4% vs. 0.3%, P=.662]. Compared to CEA, TCAR was associated with lower rates of in-hospital myocardial infarction [0.5% vs. 0.9%, P=.005], cranial nerve injury [0.4% vs. 2.7%, P<.001], and post-procedural hypertension [13% vs.18.8%, P<.001]. They were also less likely to stay in the hospital for more than one day [26.4% vs. 30.1%, P<.001]. No significant interaction was observed between procedure and symptomatic status in predicting postoperative outcomes. At one year, the incidence of ipsilateral stroke or death was similar between the two groups [HR (95%CI): 1.09 (0.87-1.36), P=.44]. This propensity-score matched analysis demonstrated significant reduction

in the risk of postoperative myocardial infarction and cranial nerve injury after TCAR compared to CEA, with no differences in the rates of stroke/death. In a more recent analysis of both high risk and standard surgical risk patients, a 2022 VQI study by Zhang GQ, et al published in the *Journal of Vascular Surgery*, compared outcomes (composite of stroke, death and myocardial infarction) using a multivariate logistic regression analysis analyzing TCAR procedures using the predicate device, TF-CAS using distal filters and CEA procedures from 2015-2020. Within the high risk patient cohort of 10,903 TCAR vs. 7,967 CEA vs. 9,896 TF-CAS procedures, TCAR demonstrated significantly lower odds of 30-day stroke, death and stroke/death and myocardial infarction for TCAR compared to both CEA and TF-CAS. Within the standard risk cohort of 4,694 TCAR vs. 33,720 CEA vs. 7,351 TF-CAS procedures, TCAR and CEA showed equivalent odds of 30-day stroke, death, and stroke/death, whereas TFCAS was associated with significantly higher risk for these endpoints. In 2023, an analysis of the National Inpatient Sample database, which is the largest all-payor inpatient database for ~35 million hospitalizations nationwide, was published by Ramsay IA, et al in the journal *Operative Neurosurgery* and queried data from 2015-2019, demonstrating the risk of stroke with TCAR was significantly lower compared to CEA with multivariate analysis (OR 0.47 (95% CI, 0.25-0.87), P = .017) and after propensity-matched analysis (OR 0.50 (95% CI, 0.25-0.97), P = .042).

TCAR Surveillance Project: Learning Curve

In a study published in the *Journal of the American College of Surgeons* in January 2020, Kashyap, et al, examined the learning curve of TCAR performed by surgeons participating in the TCAR Surveillance Project. The authors reviewed 3,456 TCAR procedures performed by 417 unique practitioners at 178 centers. Patients were grouped into four levels based upon the physicians' experience with TCAR at the time of procedure: novice (1-5 cases), intermediate (6-20 cases), advanced (20-30 cases) and expert (>30 cases). Of the patients analyzed, 41% of patients were treated by novice physicians, 40% of patients were treated by intermediate physicians, 9% of patients were treated by advanced physicians and 10% of patients were treated by expert physicians. There was no significant difference in the baseline characteristics by surgeon case experience with three exceptions; expert physicians were more likely to treat patients with moderate or severe congestive heart failure, novice and intermediate physicians were more likely to treat patients with prior CEA or CAS, and advanced and expert physicians were more likely to treat patients with CMS medical high-risk criteria. There was a statistically significant reduction in operative time (novice 81.7 mins, expert 59.6 mins; p<.001) and flow reversal time (novice 12.2 mins, expert 9.7 mins; p<.001) over the four levels. There was a decrease in fluoroscopy time and contrast usage up to the advanced level. Bleeding complications were significantly less frequent in the advanced and expert groups of physicians. There was no difference in the incidence of cranial nerve injury across the groups of physicians. Expert physicians were more likely to use local anesthesia compared to the other three categories of physicians. There was no difference in the technical failure rate across the four categories of physicians. The rate of composite stroke, stroke alone and death did not differ between the categories. The authors noted that TCAR novices can achieve the same clinical outcomes as expert practitioners, while in comparison, CAS requires more than 50 cases to achieve proficiency.

Ongoing TCAR Studies

ROADSTER 3 U.S. Post-Market Approval Study

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 Society for Vascular Surgery's Patient Safety Organization and their 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 evaluate on-label usage of the ENROUTE stent and the ENROUTE NPS for the treatment of patients at standard risk for adverse events from carotid endarterectomy who require carotid revascularization and who are eligible for treatment with these devices. The targeted enrollment in ROADSTER 3 is at least 315 patients treated per protocol at up to 60 U.S. sites. The primary endpoint is a hierarchical composite of major adverse events defined as any death, stroke or myocardial infarction within 30 days of the index procedure, plus ipsilateral stroke within 31 days to 365 days of the TCAR procedure.

Our Commercial Strategy

We believe vascular surgeons represent the specialty most frequently responsible for managing the care of and receiving referrals for patients with carotid artery disease and are skilled in endovascular procedures. Our sales, marketing, professional education and medical affairs 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 market and sell our products in the United States through a direct sales organization consisting of sales management, sales representatives, known as area managers, and clinical support specialists, known as therapy

development specialists. The area managers are typically complemented by one therapy development specialist in each territory. Our sales professionals have substantial experience launching and establishing new disruptive therapies and converting open surgical procedures to minimally-invasive alternatives. We primarily market our products directly to vascular surgeons, their staffs, operating room managers and hospital administrators. We also market to other specialists with experience in CEA and/or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology.

Our area managers are responsible for developing territory business plans, targeting and opening new accounts, promoting the benefits of TCAR and our products, and driving adoption and penetration of TCAR. Together with the therapy development specialist, they also support the training and proper use of our TCAR portfolio of products and provide clinically consultative support for patient selection, pre-procedure planning, procedure support, and post-procedure care. As we continue to grow the size of our U.S. sales organization, with a focus on increasing adoption of TCAR by existing customers and expanding our current customer base, we expect to focus on adding a strategic mix of area managers and therapy development specialists.

Our highly specialized area managers and therapy development specialists, along with other key employees, receive in-depth training and develop a thorough understanding of carotid artery disease, patient selection, imaging interpretation, procedure planning, reimbursement and regulatory policies to meaningfully support our customers and maintain compliance. Our extensive training and continuous education program consists of foundational training, procedure observation, and sales skills development. Our personnel are selected based on their focus on patient outcomes and delivering a positive customer experience in addition to their technical and clinical aptitude.

Additionally, we support our sales organization with marketing and market and practice development initiatives. We plan to continue to expand and enhance our marketing and analytics capabilities to support our growing commercial organization and customer base.

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. During the fourth quarter of 2023, we entered into an exclusive distribution agreement for our products in Japan and we submitted our updated reimbursement application during the first quarter of 2024. In addition, in the first quarter of 2023, we received approval from China's National Medical Products Administration, or NMPA, for our ENROUTE NPS. In the first quarter of 2024, we received NMPA approval for our ENROUTE stent, and we also entered into an exclusive distribution agreement for our products in China. 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. Our next steps include assessing the reimbursement process and our pathway and timeline to launch.

Professional Education

We are focused on developing strong relationships with our customers and devote significant resources to training and educating physicians in the use of TCAR and our associated products. Our Office of Medical Affairs leads our physician education and training programs in addition to disseminating the scientific information and clinical data supporting TCAR. The Office of Medical Affairs also leads compliance activities.

Our practice is to require physicians to complete a training program before performing TCAR, which is also a regulatory requirement derived from the PMA approval of the ENROUTE stent. To facilitate training, we have developed a robust training course including clinical and procedural details as well as hands-on workshops designed to provide the highest potential for successful outcomes. We conduct physician training courses in large group, in-person formats as well as virtual and small groups. We also provide training through physician proctors on an as needed basis. As of December 31, 2023, we have trained and certified over 2,800 physicians in the United States.

We offer a series of training programs for fellows and our objective is to support them in being certified to perform TCAR upon graduation from their fellowship. TCAR is now offered in most of the teaching institutions where fellows train in the United States. TCAR is also now included as part of the examination required for board certification in vascular surgery.

Coverage and Reimbursement

CMS covers carotid artery angioplasty and stenting, including TCAR, under NCD 20.7. Since September 2016, TCAR was primarily covered under NCD 20.7 indication B3, as an FDA-approved post-approval study sponsored by the Society for Vascular Surgery's VQI TCAR Surveillance Project. For providers participating in the VQI TSP, NCD 20.7 covers patients at high surgical risk for CEA who are either symptomatic with ≥50% stenosis or asymptomatic with ≥80%

stenosis, and effective May 31, 2022, CMS expanded coverage in the VQI TSP to include the standard surgical risk population. For providers not participating in the VQI TSP, TCAR was previously only covered under NCD 20.7 indication B4 for patients at high risk for CEA and who had symptomatic carotid artery stenosis >70%.

Following a request to re-open the NCD from a group of physicians labeled the MSCA in June 2022, and effective October 11, 2023, CMS published the final decision memo for NCD 20.7 expanding coverage for CAS, including TCAR, under indication B4 for both high risk and standard surgical risk patients. TCAR continues to be covered under NCD 20.7 for percutaneous transluminal angioplasty, or PTA, according to these indications:

- B3 – Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., VQI TSP)
- B4 – Concurrent with Carotid Stent Placement

Indications	B3. VQI TSP* (no change)	B4. Carotid Stent Placement (Updated 10/11/2023)	B4. Carotid Stent Placement (Original thru 10/10/2023)
Clinical Criteria			
Surgical Risk Factor Symptom Status & Degree of Stenosis	• Standard Risk & High Risk • Symptomatic & ≥50% stenosis • Asymptomatic & ≥70% stenosis		• High Risk • Symptomatic & ≥70% stenosis
Additional Criteria			
Facility Requirements	• Facility standards and approval	• Facility and physician standards for carotid stent program	• CMS facility approval and certification
Registry or Data Collection	• Registry participation (VQI-TSP)	• Not required for coverage	• Data collection
Neurological Assessments	• Not specified	• Pre & post-op neurological assessments by a neurologist or NIHSS certified HCP	• Not specified
Imaging Guidelines	• Not specified	• Duplex US and CTA/MRA or • Duplex US and DSA when non-invasive imaging is inconclusive or CTA/MRA are contraindicated	• Not specified
Shared Decision Making	• Not specified	• Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment	• Not specified

*Medicare coverage for VQI TSP is based on the study protocol (clinicaltrials.gov (NCT02850588)).

Under the revised NCD 20.7, placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device in patients with symptomatic carotid artery stenosis ≥50% and in patients with asymptomatic carotid artery stenosis ≥70% are covered under the following conditions:

(1) Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS.

(2) First-line evaluation of carotid artery stenosis must use duplex ultrasound.

(3) Computed-tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra-cranial circulation.

(4) Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results or contraindicated for CTA or MRA.

Prior to furnishing CAS, the practitioner must engage in a shared decision-making interaction with the beneficiary, which must include:

(1) Discussion of all treatment options for carotid stenosis, including CEA, CAS (which includes TCAR), and optimal medical therapy (OMT).

(2) Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.

(3) Integration of clinical guidelines (e.g., patient co-morbidities and concomitant treatments).

(4) Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. As a result of the expansion of coverage in NCD 20.7 and CMS's stated goals for broader patient access, we believe there could be rising interest and awareness in minimally invasive carotid stenting procedures including TCAR.

TCAR, like CAS, is only reimbursed by Medicare as an inpatient procedure and therefore reimbursed to hospitals under the Medicare Severity Diagnosis Related Group, or MS-DRG, system.

There are three key aspects of reimbursement in the United States: coding, coverage and payment.

- ***Coding*** refers to distinct numeric and alphanumeric billing codes that are used by healthcare providers to report the provision of medical procedures and the use of supplies for specific patients to payers. CPT codes are published by the American Medical Association and are used to report medical services and procedures performed by or under the direction of physicians. Medicare pays physicians for services based on submission of a claim using one or more specific CPT codes. Physician payment for procedures may vary according to site of service. Hospitals are reimbursed for inpatient procedures based on Medicare Severity Diagnosis Related Group, or MS-DRG classifications derived from ICD-10-CM diagnosis and ICD-10-PCS codes that describe the patient's diagnoses and procedure(s) performed during the hospital stay. MS-DRGs closely calibrate payment for groups of services based on the severity of a patient's illness. One single MS-DRG payment is intended to cover all hospital costs associated with treating an individual during his or her hospital stay, except for physician charges associated with performing medical procedures, which are reimbursed through CPT codes and payments.

- ***Payment*** refers to the amount paid to providers for specific procedures and supplies. Payment is generally determined by the specific CPT and billing code. In addition, there may be separate numeric codes, under which the billing code is classified, to establish a payment amount.

- ***Coverage*** refers to decisions made by individual payers as to whether or not to pay for a specific procedure and related supplies and if so, under what conditions, including specific diagnoses and clinical indications.

Coding for Physicians

In 2014, the Society for Vascular Surgery helped to guide an editorial change by the American Medical Association to CPT 37215 to be inclusive of TCAR. The Category I CPT code for TCAR, effective January 1, 2015, is CPT 37215: Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection. Published CMS guidance confirms that reverse flow embolic protection systems, such as our ENROUTE NPS, qualify as distal embolic protection under this code. This code has a 90-day global period. Coverage and payment for CPT code 37215 is only available from CMS in the inpatient setting, subject to the terms of the National Coverage Determination Manual Section 20.7, and facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. Hospitals participating in the VQI are considered to meet CMS's minimum facility standards.

Coding for Hospitals

There are a number of appropriate ICD-10-CM diagnosis codes that describe occlusions and stenosis of carotid arteries for asymptomatic patients as well as cerebral infarction due to embolus and thrombus of carotid arteries for symptomatic patients, which establish medical necessity. As of October 1, 2020, the proper ICD-10-PCS procedure codes for TCAR includes a code for carotid stenting [e.g. 037(H/J/K/L)3(D/E/F/G)Z] and a code for extracorporeal reverse flow neuroprotection [e.g. X2(H/J) 336]. Based on the ICD 10 diagnosis and procedure codes, TCAR inpatient admissions are assigned to MS-DRG 034 when the patient presents with major complications or co-morbidities, or MCC, 035 when the patient presents with a complication or co-morbidity, or CC, or 036 for patients without complications or co-morbidities.

Payment for Physicians

The 2024 national average physician professional fee payment for CPT code 37215 is approximately $951. We believe physicians feel this level of payment represents a reasonable amount for TCAR. CEA procedures are reimbursed under CPT code 35301, for which the 2024 national average physician professional fee payment is $1,084.

Payment for Hospitals

The Medicare national unadjusted 2024 hospital inpatient payment amounts for MS-DRGs 034, 035 and 036 are $27,316, $16,100 and $12,660, respectively. Based on prior procedure volumes assigned to MS-DRGs, we estimate that the weighted average payment amount across MS-DRGs 034, 035 and 036 is $15,785 in 2024. These MS DRG payments are intended to cover all hospital costs associated with treating an individual during his or her hospital stay, except for physician charges associated with performing medical procedures. We believe that facilities feel this level of payment represents a reasonable amount for the treatment of patients with TCAR. CEA procedures are reimbursed under MS-DRGs 037, 038 and 039. The national unadjusted 2024 payment amounts for MS-DRGs 037, 038 and 039 to be $23,635, $11,202 and $7,989, respectively. Based on prior procedure volumes, we estimate that the weighted average payment amount across these three Extracranial Procedure MS-DRGs to be $10,726. The base payment amounts for MS-DRGs may vary greatly by individual acute-care hospital for several reasons including but not limited to geographic, teaching status, case-mix index, and use of electronic health record systems.

Research, Development and Clinical Programs

Our research and development activities encompass basic research, clinical research and product development. Our engineering team has mechanical engineering, project management, materials science, and prototyping expertise. In addition, our clinical research organization has trial design, project management, data management and other clinical study operational expertise.

Our research and development efforts are currently focused on improving and expanding our portfolio of TCAR products and their labeled indications for use to further improve and simplify the treatment experience for a broad base of patients and physicians. We have worked together with vascular surgeons and other physicians to develop our products. The objective of our research and development program is to leverage our engineering capabilities, clinical and regulatory organizations, and unique insights into treatment of carotid artery disease to continue to lead the TCAR category.

Our clinical research activities are currently focused on our recently closed feasibility study in acute ischemic stroke, NITE-1, as well as completing enrollment in ROADSTER 3, our post-approval study for TCAR in standard surgical risk patients. NITE-1 results, as of the date of an abstract submission to the International Stroke Conference, were included in a poster presentation in early February 2024. Final results will be submitted in a manuscript later this year.

We also have a broad intellectual property platform addressing the transcarotid approach and, in the future, we intend to leverage our expertise to develop new products targeting market opportunities and disease states that could benefit from the physiologic and engineering advantages made possible by our transcarotid approach, including in the heart, aortic arch and brain.

For the fiscal years ended December 31, 2023, 2022 and 2021, our research, development and clinical expenses were $41.3 million, $36.4 million and $27.1 million, respectively.

Seasonality

Our revenue has fluctuated and we expect to continue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality and number of selling days. With respect to seasonality, our first quarter revenue may be harmed by adverse weather and the 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 may adversely affect procedure volumes that in turn affect hospital ordering patterns. In addition, we have also experienced moderate procedure volumes during major medical conferences when significant portions of our customer base are attending the conferences.

Competition

TCAR is a relatively new procedure category and as such the basis of competition for our products is with respect to alternative carotid revascularization procedures. We are positioning TCAR as an alternative to the existing procedures CEA and CAS, and therefore compete primarily with manufacturers of medical devices used in those procedures.

The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Inc., Getinge AB, Baxter International Inc., Terumo Medical Corporation, W. L. Gore & Associates, Inc. and Edwards Lifesciences Corporation. Many of these companies are large public companies or divisions of publicly-traded companies and have several competitive advantages, including established relationships with vascular surgeons who commonly perform the CEA procedure, significantly greater name recognition and significantly greater sales and marketing resources.

Companies with actively marketed FDA-approved stents and embolic protection devices for use with CAS procedures or which could potentially be used in TCAR include Abbott Laboratories, Medtronic plc, Boston Scientific Corporation, and Cordis Corporation. Other companies have approved devices not currently marketed in the U.S., including W. L. Gore & Associates, Inc., Terumo Medical Corporation, Contego Medical Inc. and InspireMD, Inc. Additionally, some companies have stents and other products in ongoing IDE or planned IDE trials in the U.S., including Terumo Medical Corporation, Contego Medical Inc. and InspireMD, Inc. Preliminary results from Contego Medical Inc.'s PERFORMANCE II and InspireMD, Inc.'s C-Guardians studies were presented at the Vascular InterVentional Advances, or VIVA, conference in November 2023. Contego Medical Inc. and InspireMD, Inc. have also announced plans to develop products for TCAR. Many of these companies have several competitive advantages including the following: more established sales and marketing programs and networks, larger portfolio of products, longer operating histories, established relationships with healthcare professionals and greater name recognition.

Some competitors market other endovascular products that can be used in CAS and TCAR, such as peripheral access kits, guidewires, stents, balloons and sheaths. Such companies include but are not limited to Abbott Laboratories, Boston Scientific Corporation, Cordis Corporation, Medtronic plc and Cook Medical Inc.

In addition to competing for market share for TCAR, we also compete against these companies for personnel, including qualified personnel that are necessary to grow our business.

We believe the principal competitive factors in our market include the following:

- Patient outcomes and adverse event rates;
- Patient experience;
- Acceptance by treating physicians and referral sources;
- Physician learning curve;
- Ease-of-use and reliability;
- Patient recovery time and level of discomfort;
- Economic benefits and cost savings;
- Price;
- Availability and amount of reimbursement; and
- Strength of clinical evidence.

We also compete against manufacturers of medications used for medical management of carotid artery disease, including aspirin and statins. Many such companies are large public companies or divisions of publicly-traded companies and have several competitive advantages including the following: established treatment patterns where drugs are generally first-line therapy and invasive procedures or surgery are considered later; established relationships with general practitioners who commonly prescribe such medications; significantly greater name recognition; and significantly greater sales and marketing resources.

Intellectual Property

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology and products, proprietary processes and any other inventions that are commercially or strategically important to the development of our business. We also rely upon trademarks to build and maintain the integrity of our brand, and we seek to protect the confidentiality of trade secrets that may be important to the development of our business.

To protect our proprietary rights, we rely on a combination of trademark, copyright, patent, trade secret and other intellectual property laws, employment, confidentiality and invention assignment agreements, and protective contractual provisions with our employees, contractors, consultants, suppliers, partners and other third parties.

As of December 31, 2023, we owned 179 patents globally, of which 78 were issued U.S. patents and 101 were patents outside of the United States. Our patents expire between November 2024 and July 2039. Our material patents, their jurisdiction, expiration date and the product to which they relate, are listed in the table below:

Jurisdiction	Patent No.	Expiration Date	Related Product
US	8,002,728	12/2/2025	Transcarotid Neuroprotection System
US	8,343,089	6/22/2025	Transcarotid Neuroprotection System
			Transcarotid Stent System
US	8,157,760	9/3/2030	Transcarotid Neuroprotection System
US	8,784,355	8/7/2029	Transcarotid Neuroprotection System
US	8,740,834	3/6/2029	Transcarotid Neuroprotection System
US	9,011,364	4/10/2031	Transcarotid Neuroprotection System
US	9,833,555	10/26/2029	Transcarotid Neuroprotection System
US	10,238,853	5/16/2039	Transcarotid Neuroprotection System
Europe	2,173,425	7/18/2028	Transcarotid Neuroprotection System
France	2,173,425	7/18/2028	Transcarotid Neuroprotection System
Germany	2,173,425	7/18/2028	Transcarotid Neuroprotection System
Italy	2,173,425	7/18/2028	Transcarotid Neuroprotection System
Great Britain	2,173,425	7/18/2028	Transcarotid Neuroprotection System
Japan	5,290,290	7/18/2028	Transcarotid Neuroprotection System
Japan	5,693,661	7/18/2028	Transcarotid Neuroprotection System

As of December 31, 2023, we had 96 pending patent applications globally, including 41 in the United States and 55 outside the United States.

As of December 31, 2023, we had trademark registrations for “Silk Road Medical,” the “Silk Road Medical” logo, “TCAR,” “Enroute” and the “Enroute” logo and “Enhance” in the United States, and various other countries. Including these trademark registrations, our trademark portfolio contained 101 trademark registrations/applications.

We also seek to maintain certain intellectual property and proprietary know-how as trade secrets, and generally require our partners to execute non-disclosure agreements prior to any substantive discussions or disclosures of our technology or business plans. Our trade secrets include proprietary account analytics, user training methods, and operational processes. For more information, please see “Risk Factors—Risks Related to Intellectual Property.”

Manufacturing and Supply

We currently manufacture the ENROUTE NPS and ENROUTE NPS PLUS, or our ENROUTE NPS products, at our facilities in Sunnyvale, California and Plymouth, Minnesota. These facilities provide an aggregate of approximately 35,000 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our combined facilities will be sufficient to meet our manufacturing needs for at least the next five years.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA’s Quality System Regulation, or QSR, for medical devices sold in the United States, set forth in 21 CFR part 820. Our quality system is also certified as demonstrating compliance to ISO 13485:2016. In July 2022, we voluntarily requested the cancellation of our CE Mark certifications for business reasons but will continue to work with our Registrar to maintain ISO 13485:2016 certifications of our quality system for both our Sunnyvale and Plymouth facilities. We may seek new CE Mark certifications in the future. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

The FDA monitors compliance with the QSR through periodic inspections of our facilities. Our suppliers’ facilities are also subject to FDA regulations, including the QSR, and unannounced inspections by the FDA and other similar regulatory authorities. Our Registrar for ISO 13485:2016, British Standards Institute, or BSI, monitors compliance to the standard’s requirements through annually scheduled audits of our manufacturing facilities.

We have been an FDA registered medical device establishment and California licensed medical device manufacturer since 2011. We completed the initial FDA registration of our Plymouth, Minnesota facility in May 2022.

The FDA has conducted a total of five establishment inspections of our manufacturing facility in Sunnyvale, California. The most recent inspection in 2023 concluded with no actions indicated. The FDA conducted an initial facility inspection in our Plymouth, Minnesota location in January 2024 and a one-observation Form 483 Notice of Observation was issued

pertaining to a singular piece of production equipment in relation to calibration and preventive maintenance. In response, we initiated a Corrective and Preventive Action, or CAPA, to address the 483. We believe that we are in compliance, in all material respects, with all applicable FDA requirements, including the QSR.

Since obtaining ISO 13485 certification in 2011 for the Sunnyvale facility, BSI has conducted scheduled surveillance audits annually, recertification audits every third year, and periodic audits since the initial certification period. The most recent recertification audit for Sunnyvale was conducted in September 2023 and no major non-conformities were identified. The initial ISO 13485:2016 certification of the Plymouth facility was completed in November 2023, with no major non-conformities identified. We are no longer subject to unannounced audits since our CE Mark certifications have been canceled. We believe that we are in compliance, in all material respects, with all ISO 13485 requirements.

Manufacturing of the materials and components of the ENROUTE NPS products are provided by approved suppliers, some of which are single-source suppliers of key components, sub-assemblies and materials. We purchase finished transcarotid access kits, guidewires, balloons and stents through contract manufacturers. Cordis is our contract manufacturer and currently the sole source supplier for the ENROUTE stent. We typically maintain several months' worth of ENROUTE stents in inventory, and we estimate that it would take up to two years or more to qualify a second source supplier for our ENROUTE stent. The suppliers for our ENROUTE NPS products and our other product lines are evaluated, qualified and approved through a stringent supplier management program, which includes various evaluations, assessments, qualifications, validations, testing and inspection to ensure the supplier can meet acceptable quality requirements. We ensure a strict change control policy with our key suppliers to ensure that no component or process changes are made without our prior approval.

Order quantities and lead times for components purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components, sub-assemblies and materials. We typically stock several months of supply for components and raw materials to mitigate any supply delays or disruptions. Considering ongoing global supply chain constraints, we are working with all our suppliers on additional orders and forecasting to mitigate any potential supply issues. We perform assembly, testing, inspection and final product release activities for the ENROUTE NPS. Finished ENROUTE NPS devices are ethylene oxide sterilized at a qualified supplier.

Cordis License Agreement

In December 2010, we entered into a license agreement with Cordis, which agreement was amended in May 2023 (as amended, the Cordis License Agreement). Pursuant to the Cordis License Agreement, Cordis granted us a worldwide, non-exclusive, perpetual, royalty-bearing license to certain of its intellectual property related to the PRECISE carotid stent, or the Licensed IP, for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. Cordis may not license the Licensed IP in our licensed field of use to any other third party during the term of the Cordis License Agreement.

The Cordis License Agreement requires us to work exclusively with either Cordis or Confluent Medical Technologies, Inc. (f/k/a Nitinol Devices and Components, Inc.), or Confluent, for the development, manufacture and supply of the licensed products. If either Cordis or Confluent cannot continue to manufacture or supply the licensed products, we can seek a third-party manufacturer with the prior written consent of Cordis.

We have the right to assign or transfer the Cordis License Agreement to an entity that succeeds all or substantially all of our equity or assets. The Cordis License Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 60 days (or 30 days for payment related breaches), or bankruptcy of the other party.

Cordis Supply Agreement

In October 2011, we entered into a supply agreement with Cordis and have since entered into several amendments, most recently in May 2023 (as amended, the Cordis Supply Agreement). Pursuant to the Cordis Supply Agreement, Cordis has assisted in the development of a transcarotid stent delivery system according to our specifications with a PRECISE carotid stent implant, or ENROUTE stent and has supplied the ENROUTE stent through preclinical and clinical trials. Cordis has agreed to supply the ENROUTE stent for our commercial sale through February 19, 2029 and has agreed to engage in good faith negotiations to extend its supply commitment beyond that date. Cordis has the exclusive right to manufacture and supply the current generation of the ENROUTE stent during the term of the Cordis Supply Agreement. If Cordis is not able to supply the ENROUTE stent, upon our election, Cordis shall permit Confluent or a third-party manufacturer to provide supply of the ENROUTE stent, provided that Cordis retains the right to manufacture and supply the ENROUTE stent to us to the extent it is able to do so. The Cordis Supply Agreement requires a specified

minimum volume purchase commitment from us 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.

The Cordis Supply Agreement will continue in full force and effect until the earlier to occur of (i) termination of the Cordis License Agreement; (ii) our election if and when Cordis approves another manufacturer; (iii) mutual written termination; or (iv) termination pursuant to the terms therein. The Cordis Supply Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 30 days, or bankruptcy of the other party.

Government Regulation

United States Food & Drug Administration

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. In some cases, where no predicate device exists, Class II devices may come to market through the de novo authorization process. The 510(k) clearance, de novo authorization, and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device Classification

Under the FDCA, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

If a new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and

Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and Institutional Review Board. or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) Clearance Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. 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.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. The Medical Device User Fee Amendments sets a performance goal of 90 days for FDA review of a 510(k) submission, but the review time can be delayed if FDA raises questions or requests additional information during the review process. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. A

manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained.

More recently, in September 2019, the FDA finalized 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 intends to develop and maintain 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 De Novo Process

Medical devices that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. De novo classification requests are also subject to the payment of user fees. Under FDASIA, the FDA is required to make a decision within 120 days following receipt of the de novo request, but the process may take significantly longer.

If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If the FDA grants the de novo request, the device may be legally marketed in the United States. However, the FDA may reject the request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and/or special controls cannot be developed.

Once a device receives a de novo classification as a Class II device, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another de novo request or even PMA approval.

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily

withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA's satisfaction;
- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data is available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, 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 or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

Japan Pharmaceuticals and Medical Devices Agency

Japan maintains a regulatory framework, similar to that described for the United States, under its Pharmaceutical and Medical Device Act, or PMD Act. The PMD Act covers regulations on pharmaceuticals, medical devices, and cosmetics and is governed by the Ministry of Health, Labor, and Welfare, or MHLW, which has the authority to (1) issue marketing licenses, (2) issue Marketing Authorization Holder licenses, and (3) issue Foreign Manufacturer Registration, or FMR, licenses, among its other responsibilities in policies and administrative measures. Within the MHLW, the Pharmaceuticals and Medical Devices Agency, or PMDA, performs the technical management and review of medical devices including, but not limited to, (1) review, examination, analysis, and approval recommendations, (2) Quality Management Systems, Good Laboratory Practice, and Good Clinical Practice inspections, and (3) collection and analysis of Post Market Surveillance data.

Our portfolio in Japan is subject to the PMD Act regulatory framework. Like the FDCA regulatory framework, medical devices must be classified into one of four classes - Class I, Class II, Class III, or Class IV - depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect

to safety and effectiveness. Our devices are classified as Class IV, Specially Controlled Medical Devices, with a regulatory pathway that requires MHLW approval (Shonin pathway).

Pursuant to the Shonin regulatory pathway, the PMDA may conduct audits to verify compliance with Good Clinical Practice, Documentation Reliability, and Quality Management System standards and/or regulations, in addition to inspections of the manufacturing facility and processes. Often, in the case of novel device approvals, the PMDA may 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 PMDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device.

There are several additional pre-requisites that are required of medical device manufacturers to obtain approval for market authorization in Japan. These include the appointment of a Marketing Authorization Holder in Japan and the acquisition of an FMR. Only a Marketing Authorization Holder, or MAH, a Japanese domestic medical device manufacturer, or a Designated Marketing Authorization Holder, or DMAH, a designee by an overseas medical device manufacturer, may import and sell medical products to the Japanese market. Additional duties of the MAH/DMAH include, but may not be limited to, the following:

- Facilitating PMDA product registration, managing product license modifications, and maintaining product approvals;
- Managing product quality and safety to ensure that manufacturing sites comply with Japan's Quality Management System requirements;
- Managing product storage in the Japanese market;
- Administering product release to distributors in the Japanese market; and
- Managing post-market surveillance in the Japanese market.

If the PMDA evaluation of a Shonin application is favorable, MHLW may then issue the applicant a license for the product. This product license does not have an expiration date, however, the FMR and QMS conformity certificate expires every five years and requires renewal to keep the product in compliance on the Japanese market.

China National Medical Products Administration

China maintains a regulatory framework for medical devices directed by State Decree No. 739, "The Regulations on the Supervision and Administration of Medical Devices". State Decree No. 739 outlines regulations on the following elements, (1) General Provisions, (2) Medical Device Product Registration and Filing, (3) Medical Device Production, (4) Operation and Use of Medical Devices, (5) Handling of Adverse Events and Recall of Medical Devices, (6) Supervision and Inspection, and (7) Legal Liability. The Chinese NMPA is charged with the administration of these regulations and coordinates its supervision with other governmental bodies, (i.e., Center for Medical Device Evaluation, Center for Medical Device Standardization), to ensure that devices registered, imported/exported, manufactured, sold, or used in the Chinese market are safe and effective.

Our portfolio in China is subject to the State Decree No. 739 framework. Manufacturers of medical devices must classify those devices into one of three categories - Class I, Class II, or Class III - depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Our devices are classified as Class III, a higher-risk device category requiring special measures to be strictly controlled and managed to ensure safety and effectiveness and which are subject to product registration.

Pursuant to the regulatory framework in China, manufacturers must demonstrate the following in order to successfully gain approval for a medical device:

- Appoint a Legal Agent in China;
- Obtain foreign market approval, (typically either FDA clearance/approval or EU certificate);
- Obtain certification of a Quality Management System (typically ISO 13485 certification);
- Prepare Chinese specific Product Technical Requirements (PTR); and

- Perform successful Type Testing of the product per established PTR.

The legal agent in China is a domestic representative (or service) who acts as an interface with the Chinese regulatory bodies in both pre-market and post-market phases of any medical device distributed in China. Often, a distributor serves as both the domestic distributor and the legal agent if that distributor has the appropriate Chinese licensing to do so. Additional duties of the legal agent include, but may not be limited to, the following:

- Performs product registration/filing for overseas manufacturers;
- Performs domestic post market surveillance duties, (e.g., Adverse Event reporting, recall coordination, customer compliant collection, etc.);
- Assists NMPA with inspection and quality evaluation of overseas manufacturers; and
- Manages and monitors medical device importation, sales, and distribution in China.

If the NMPA evaluation of the medical device filing is favorable, the applicant is issued a license for the product. This product license has a five (5) year expiration period and must be renewed prior to license expiry for the product to continue to be imported, sold, or distributed in China.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- The FDA, NMPA, and PMDA QSR, which require manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA, NMPA, and/or PMDA if their device 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;
- Medical device recalls, which require that manufacturers report to the FDA, NMPA, and PMDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA, State Decree No. 47, or PMD Act caused by the device that may present a risk to health; and
- Post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and a specification developer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA and CDPH have broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Additionally, our Registrar, BSI, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485 compliance. Further, in February 2024, the FDA issued a final rule replacing the QSR with the Quality Management System Regulation, or QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026.

We maintain a Foreign Manufacturer Registration with Japan’s MHLW which requires assessment of the quality system by PMDA on an ongoing basis. We also maintain a DMAH in the Japanese market that has been appropriately recognized by MHLW, which oversees quality management and operations in the Japanese market for our products licensed in Japan. Similarly, we maintain a legal agent in the Chinese market that has been appropriately recognized by NMPA, which oversees quality management and operations in the Chinese market for our products licensed in China.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, NMPA, or PMDA, which may include any of the following sanctions:

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recall or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our requests for submissions, including 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, or license modifications;
- Withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

Compliance

Our compliance organization is designed to support our growing organization through an effective Corporate Compliance Program based on our legal and regulatory environment. Our compliance and ethics programs support our key business objectives, identify legal and ethical behavior boundaries through our code of conduct, and establish a system to inform leadership. Primary responsibilities of our compliance organization are as follows:

- Healthcare compliance program development and implementation;
- Existing program evaluation through risk assessment and internal audits;
- Compliance issue investigation and remediation;
- Corporate compliance training and education; and
- HIPAA privacy training.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, established federal protection for the privacy and security of health information. Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by “Covered Entities,” including healthcare providers and their Business Associates. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures. HIPAA requires Covered Entities to execute Business Associate Agreements with their Business Associates and subcontractors, who provide services to Covered Entities and who need access to protected health information. In addition, companies that would not otherwise be subject to HIPAA may become contractually obligated to follow HIPAA requirements through agreements with Covered Entities and Business Associates, and some of our customers may require us to agree to these provisions.

In addition, HIPAA and other federal privacy regulations, such as Section 5 of the Federal Trade Commission Act, there are a number of state laws regarding the privacy and security of health information and personal data that apply to us. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely, and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely.

If we or our operations are found to be in violation of HIPAA, HITECH, or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave

state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

U.S. Federal, State and Foreign Fraud and Abuse Laws

The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. 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.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. 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 exclusion from participation in government healthcare programs, including Medicare and Medicaid. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act.

The Office of Inspector General, or OIG, of the HHS has issued a series of regulations known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is per se illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Act

The federal False Claims Act, or FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payer and not only a federal healthcare program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil fines and penalties for each false claim, subject to adjustment for inflation. As part of any settlement, the government may require the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer faces liability for "causing" a false claim. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and

third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

Civil Monetary Penalties

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or 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.

Open Payments

The Physician Payments Sunshine Act, known as "Open Payments" and enacted as part of the Affordable Care Act, requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value to 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. Failure to submit required information on time may result in civil monetary penalties with additional amounts for knowingly failing to submit payment information. We are subject to Open Payments and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

International Laws

Outside of the United States, we are subject to medical device laws and other applicable laws in countries where we operate or commercialize our medical devices. In addition to medical device laws, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, under the U.K. Bribery Act 2010, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Centers for Medicare and Medicaid Services

Medicare is a federal program administered by the U.S. Centers for Medicare and Medicaid Services through fiscal intermediaries and carriers. Available to individuals age 65 or over, and certain other individuals, the Medicare program

provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our products could have a material effect on our performance.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement vary from state to state and is subject to each state's budget restraints. Changes to the availability of coverage, method or level of reimbursement for TCAR may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for TCAR.

United States Health Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The ACA substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and 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.

Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. It is unclear how efforts to repeal and replace the ACA will impact the healthcare industry or our business operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless Congress takes additional action. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS 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.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose

additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payers. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Human Capital

Our mission is to help deliver brighter patient outcomes - one procedure at a time. We recognize that our employees are key to our ability to achieve this mission and believe our employees have been and will continue to be a primary reason for our growth and success.

Recognizing the importance of our human capital, our board of directors, through the compensation committee, retains direct oversight of our human capital and oversees and reviews our culture, policies, and strategies related to human capital management, including with respect to diversity and inclusion initiatives, pay equity, talent, recruitment and development, performance management and employee engagement.

We are a certified Great Place to Work,® which certification is the only recognition based entirely on what employees report about their workplace experience. 97% of our employees say Silk Road Medical is a great place to work, compared to 57% of employees at a typical U.S.-based company, according to a Great Place To Work® 2023 Global Employee Engagement Study. We take pride in our company culture to ensure a sense of support and family among our employees.

Our Cartwheel Culture: Building and Supporting Human Capital

We understand the commitment our employees make to our company, and we take our commitment to them very seriously. Consistent with this commitment, we strive to create a work environment in which everyone is empowered to develop, to contribute, and to thrive. We strongly believe our corporate culture is the operating system that powers the company. We talk about it, obsess over it, and have even given it a name – Cartwheel Culture.

Our Cartwheel Culture is uniquely ours, and it's one we love and nurture every day. Our Cartwheel Culture provides a shared set of beliefs that drives everyday behaviors. These include:

- Courage: We think big. We act boldly. We take on new challenges. We challenge ourselves and our colleagues to try new things that are difficult. We take smart risks. We explore new ideas and do things differently.

- Focus on Core Strength: We unleash our strengths and shore up weaknesses in our company, in every department and in each member of our company.

- Flexibility: We view opportunities and challenges from all angles…even upside down. We explore all possibilities and are both willing and able to respond to changing circumstances and expectations. We make it a priority to listen and understand other people's ideas and viewpoints.

- Lend a Hand: We actively support each other to achieve our common goal. Teamwork Matters.

- Persistence: We believe that innovation comes from persistence and learning from our mistakes. We are persistent in the pursuit of our goals and believe that it's better to try and sometimes fail than to sit tight and fail for sure. We learn from the mistakes we make and move forward.

Code of Business Conduct and Business Ethics

All employees are expected to conduct business with the highest standards of business ethics. Each employee receives and agrees to follow our Code of Business Conduct and Ethics. Our Code of Business Conduct and Ethics does more than just codify rules of conduct - it is the very foundation by which we conduct business every day. The Code of Business Conduct and Ethics, which also applies to our board members, describes how we put our values into practice, and it explains our commitments, our expectations and provides guidance for our employees and all others who work on our behalf. Our employees receive annual training on our Code of Business Conduct and Ethics. We have an open access policy, signifying that employees are encouraged to discuss any related concerns with management or report concerns anonymously through an Integrity Helpline.

Number of Employees, Tenure and Turnover

Our workforce consists of a highly-skilled, diverse, and engaged team dedicated to the company's mission and goals. As of December 31, 2023, we had 474 active employees, all located within the United States, of whom 264 employees were engaged in sales, general and administrative activities, 95 were engaged in research and development activities, and 115 were engaged in manufacturing operations. During 2023, the number of employees increased by 60, or nearly 15%. None of our employees are represented by a labor union, and we have never experienced any employment-related work stoppages. We consider our relationship with our employees to be good.

As of December 31, 2023, 28% of our employees had been with Silk Road Medical for more than four years. While fluctuations may occur within our workforce from time to time, we track and attempt to manage our attrition rates and also analyze employee departure data so that we can continually improve upon our employee experience. During 2023, our employee turnover rate related to voluntary terminations was approximately 8%, which was 3% lower than the prior year.

Commitment to Diversity, Equity, and Inclusion

We strive to create an inclusive work environment that represents the diversity in the communities where we live and work, and we are proud of the diversity throughout our entire organization. In late 2022, we formed a Diversity, Equity, and Inclusion (DEI) Council with the mission of fostering an environment that is inclusive and welcoming to all. The Council started work with a climate assessment survey and baseline training to bring awareness, engage employees on the topic of inclusion, and create a common language. The Council's work expanded in 2023 with a focus on employee education, cultural awareness, and DEI awareness in our HR and marketing programs.

As of December 31, 2023, women made up approximately 46% of our workforce, including 38% of our senior level leaders and 48% of our total corporate leaders. People of color made up approximately 44% of our workforce, including 21% of our senior level leaders and 27% of our total corporate leaders.

Our workforce spans approximately four generations. Baby Boomers make up about 10% of our workforce, GenX makes up about 46% of our workforce, Millennials make up about 38% of our workforce, and GenZ makes up about 6% of our workforce.

We believe that it is important to have a balanced and diverse board of directors and are committed to building and maintaining director diversity with members who bring a range of expertise, perspectives, experiences, and personal characteristics pertaining to age, race, gender, and ethnicity. As of December 31, 2023, our board of directors, which consisted of eight members, included two female directors and two directors who self-identify as an underrepresented minority.

In addition, we actively recruit candidates from a variety of backgrounds and work to ensure a fair interview and selection process. We are also active in building a diverse pipeline of candidates through our Summer @ the Road internship program. We have partnered with organizations such as East Side Prep in East Palo Alto, California, and diversity groups at several universities from which we recruit students. In 2023, we had 13 interns with 77% being people of color and 67% of engineering interns being women. Five interns accepted full-time jobs starting in 2024.

Commitment to Creating a Safe, Healthy, and Secure Work Environment

We are committed to providing a safe, healthy and secure work environment for all employees and visitors. Safety is extremely important to the company. We have developed and implemented several health and safety programs throughout our facilities with employees' safety in mind. These programs include an Injury and Illness Prevention/AWAIR Program, an Emergency Action Plan, an Ergonomic Program, an Exposure Control Plan, a Hazard Communication Program, a Hazardous Waste Management Program, and other specialized safety programs. We support these programs and allot time for safety training. In addition, any employee working in a hospital operating room is required to wear a dosimetry badge that monitors occupational radiation exposure to ensure compliance with annual limits. Our Employee Safety Committee reviews performance monthly to discuss trends and risks, as well as opportunities for improvement. We have in place an Employee Emergency Response Team comprised of volunteers trained in First Aid, CPR, AED operation and site-specific emergency procedures. We are proud of our safety record. During 2023, our total recordable injury rate was 1.1, which is below the average for the medical device manufacturing industry. The total recordable injury rate is a standard metric comparing recordable injury rate per 100 employees.

Commitment to Competitive and Fair Compensation

We place a focus on attracting and retaining talented and experienced individuals to manage and support our operations and believe that employees should be compensated fairly for their contributions to the company. To ensure we

pay our employees competitively, annual benchmarking is completed on all positions throughout the company and we use external benchmarking surveys to guide our assessment of compensation competitiveness. Our compensation program consists of three primary components: base salary, annual bonus targets (non-sales), commission plans (sales), and equity. We also offer all eligible employees the option to participate in our Employee Stock Purchase Plan or ESPP. Participants in the ESPP may purchase our common stock at a 15% discount to market price. We believe our ESPP plan, along with our new hire equity grants and refresh equity grants, helps to build an ownership mindset amongst our participating employees.

Commitment to the Health and Wellbeing of our Employees

One of our top priorities is to maintain the health and well-being of our employees and their families. We offer a comprehensive health and wellness program with a variety of options for eligible employees. Health benefits include three medical plans, dental, and vision insurance. The company covers 90% of health care premiums on behalf of our employees. Financial wellness benefits include life and disability insurance, flexible spending accounts, a health savings account with generous employer funding, a 401(k)-retirement savings program with a company match, paid time off for employees in non-exempt positions, flexible time away for employees in exempt positions, and 160 hours of child bonding pay. Additional wellness discounts and perks are offered through our health carriers. Well-being offerings include an employee assistance program, a fitness benefit of $50 a month to be used toward the fitness method of choice, a company wellness app with fitness challenges and monetary incentives, and flexible work arrangements for positions that can be performed remotely from one of our primary work locations.

Commitment to Learning and Development; Succession Planning

We believe that the professional development of our employees is a critical element to the success of our company. We have invested in a robust learning and development program that provides employees at all levels of the company opportunities to build and grow their skills in their current roles and prepare them for future roles in the company.

We have an extensive training and development program in place for our salesforce that includes a robust clinical training continuum for our therapy development specialists, area managers, and area directors. Upon hire, these employees attend a training program that includes intensive clinical/practical application training the observation of live TCAR cases, followed by intermediate training with advanced clinical education. Employees in these roles also attend regular continuing education courses on clinical topics to ensure their knowledge is current.

We also actively support the professional education of employees throughout the organization, with a special focus on leadership development. We've both internally developed and thoughtfully sourced respected external programming to provide intrapersonal development as well as classes to support key professional skill sets for daily tasks, including software tools and applications. Development opportunities are thoughtfully scheduled and promoted to reach all employees with in-person classes in both physical sites and virtual class opportunities to serve the field-based employee population.

On an annual basis, our leadership team participates in talent planning exercises to identify organizational priorities, potential successors, and development needs. This practice enables us to identify the resources and skill sets needed to meet our growth objectives. Our board of directors also conducts an annual talent management review, focusing on the development of talent, diversity, and succession planning for critical positions.

Employee Engagement

We provide all employees with the opportunity to share their opinions and feedback on our culture through an engagement survey that is generally performed every year. Results of the engagement survey are measured and analyzed to enhance the employee experience, promote employee retention, drive change, and leverage the overall success of our organization. Our strong employee response was indicative of our engagement, with 82% of employees participating in the most recent survey.

Commitment to Corporate Philanthropy

Through our corporate philanthropy program, Lend a Hand, we are committed to supporting social causes and educational initiatives that help build stronger and healthier communities. Over the years, we have been involved in a variety of projects, including holiday gift drives, school backpack drives, the hand-making and donation of blankets to a local rehabilitation and healthcare center near our Sunnyvale, California headquarters, participation in the Stroke Awareness Foundation’s Fight Stroke Walk, and building bikes for underprivileged children.

Additional Information

Additional information about our human capital and people, including our culture; employee health and safety; diversity, equity and inclusion; talent attraction, retention and development; employee wellness; and community involvement and engagement, is included in our most recent Corporate Responsibility Report, which is available under the Corporate Governance section on our website. Information contained or referenced on our website is not incorporated by reference and does not form a part of this Annual Report on Form 10-K.

Corporate Information

We were incorporated in Delaware on March 21, 2007 as Silk Road Medical, Inc. Our principal executive offices are located at 1213 Innsbruck Drive, Sunnyvale, California 94089, and our telephone number is (408) 720-9002. Our website address is www.silkroadmed.com.

Available Information

We file electronically with the SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make available on our investor relations website at https://investors.silkroadmed.com/, free of charge, copies of these reports and other information as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Investors and others should note that we announce material financial information to our investors using SEC filings, press releases, our investor relations website, public conference calls and webcasts. We use these channels as well as social media to communicate with investors, customers and the public about our company, our products and other issues. It is possible that information we post on social media channels could be deemed to be material information. The information on, or that may be accessed through, our website and social media channels is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

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 Annual Report on Form 10-K, including our 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 total market opportunity for TCAR and our ability to penetrate it through 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.

- 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.

- We are highly dependent upon our sales personnel. In addition, during 2023, we expanded our sales and marketing infrastructure, including the number of sales personnel and sales territories, to help us drive and support revenue growth. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023 and may continue to adversely affect our revenue through the first half of 2024.

- Our actual operating results have differed in the past, and in the future may differ, significantly from our guidance, which has caused, and could continue to cause, the market price of our common stock to decline.

- Our failure to manage the transition associated with our Chief Executive Officer, retain our existing senior management team, or continue to attract qualified new personnel could have a material adverse effect on our business.

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 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 and other reimbursement requirements, such as those in revised NCD 20.7, 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 year ended December 31, 2023, we had a net loss of $55.7 million and we expect to continue to incur additional losses in the future. As of December 31, 2023, we had an accumulated deficit of $399.5 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. Our ability to generate sufficient revenue from our existing products or from any of our products in development, to transition to profitability and generate consistent positive cash flows, is uncertain. 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 or within a timeline expected by investors 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.

While we believe we will continue to grow our revenues, we may be unable to sustain our historical revenue growth.

Our revenue from sales of our TCAR products has grown in each of the fiscal years since we began commercialization in 2015 and we believe it will continue to grow. Historically, we have experienced significant revenue growth but we may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior quarterly or annual period as an indication of our future operating performance. Our ability to increase our revenue in future periods at our historical growth rates, or at all, will depend primarily on our ability to increase sales of our TCAR products, which, in turn, will depend in part on our success in growing our customer base and reorders from those customers. We may not be able to generate, sustain or increase revenue from our TCAR products on a quarterly or annual basis. If we cannot achieve or sustain revenue growth for an extended period, our operating results may be adversely affected and our stock price may decline. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a shortfall relative to our anticipated revenue could magnify the adverse impact of such shortfalls on our results of operations.

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, including without limitation, the approval or substitution of other stents that could be used in TCAR procedures and the effect of competing products on the average selling prices of our products, and changes in reimbursement for our products and competing products.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the market opportunity for TCAR or 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 total market opportunity for TCAR and our ability to penetrate it through continued adoption of TCAR by hospitals and physicians.

Our future growth and profitability largely depend on the total market opportunity for TCAR, the determination of which is inherently imprecise, and our ability to penetrate it, which is largely dependent upon 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. While we are confident in our estimate of the annual total addressable market for our TCAR products, especially since it is based on a number of internal and third-party estimates, it may prove to be incorrect. If the actual number of patients who would benefit from our products and the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. With respect to our ability to penetrate this market opportunity, 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 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;
- Lack of experience with TCAR as a treatment alternative to CEA;
- Familiarity and experience with 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.

While we believe the revised NCD 20.7 for Percutaneous Transluminal Angioplasty will lead to benefit carotid artery disease awareness in general and help grow the overall carotid intervention market, which would be a potential positive for all carotid interventions, including TCAR, no assurance can be provided that this will prove true. In addition, while we believe the higher associated procedural stroke risk for transfemoral carotid artery stenting and steep learning curve will continue to limit the pool of eligible patients and skilled interventionalists, thereby limiting the growth potential for transfemoral CAS in the near term, no assurance can be provided that this will prove true either. During CMS review of the clinical literature and as suggested by the Multispecialty Carotid Alliance, or MSCA, CMS considered evidence published from the ACT I, CREST (long-term results), SPACE-2 and ACST-2 randomized controlled trials of CAS versus CEA, amongst other datasets. As well, in November 2023, preliminary results of newer CAS technologies in the PERFORMANCE II and C-Guardians IDE studies were presented at the late-breaking trials session Vascular InterVentional Advances, or VIVA, conference. Physicians may find these data compelling and may be more willing to try the newer transfemoral CAS products at the expense of our TCAR procedure, especially in the near term and as a result of revised NCD 20.7. Accordingly, it is possible that we may experience increased future competition from stents and embolic protection devices for CAS based on the revised NCD 20.7, which could adversely affect our revenue, other financial results and business.

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. This is particularly true in light of the new requirement in revised NCD 20.7 which requires a practitioner to engage in a shared decision-making interaction with the beneficiary prior to furnishing CAS. We focus our sales, marketing and education efforts primarily on vascular surgeons, and aim to educate referring physicians such as internal medicine specialties, 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.

In addition, if patient receptivity toward TCAR becomes less favorable in the future, this shift could negatively impact market acceptance of TCAR. Any negative change due to patient receptivity could also be compounded by patients reporting to physicians or other patients through word-of-mouth or social media.

Finally, the total market opportunity for TCAR could decrease if glucagon-like peptide (GLP-1) agonists are prescribed more broadly and result in less cardiovascular disease including carotid artery disease and overall fewer strokes over the long term.

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 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. The CEA trial completed enrollment in the fourth quarter of 2023. We project the CAS trial to complete enrollment later in 2024 followed by a mean follow-up period of four years. The national principal investigators have stated that results will not be published until 2026. 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 Society for Vascular Surgery, 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 Society for Vascular Surgery'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 Society for Vascular Surgery 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, adversely 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 are concerned with the ability of a critical supplier of certain

polymer tubing materials used in our products to provide us and 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, Nordson Medical for our balloon catheters, and Galt Medical for our transcarotid access kits, 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 or other 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, or otherwise have an adverse impact on our results of operations and financial condition. 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. General macroeconomic factors also may affect our customers, vendors and suppliers and their ability to pay us or continue to supply us products and services, which could also adversely affect our results of operations or financial condition.

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, 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. 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.

CMS released the final decision update to NCD 20.7, expanding the Medicare coverage of carotid artery stenting. CMS determined 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 a 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% under the following conditions:

(1) Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS.
(2) First-line evaluation of carotid artery stenosis must use duplex ultrasound.
(3) Computed-tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra-cranial circulation.
(4) Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results or contraindicated for CTA or MRA.

Prior to furnishing CAS, the practitioner must engage in a shared decision-making interaction with the beneficiary. The shared decision-making interaction must include:

(1) Discussion of all treatment options for carotid stenosis including, carotid endarterectomy (CEA), CAS (which includes TCAR), and optimal medical therapy (OMT).

(2) Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.
(3) Integration of clinical guidelines (e.g., patient co-morbidities and concomitant treatments).
(4) Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. While we believe the revised NCD 20.7 will benefit carotid artery disease awareness in general and help grow the overall carotid intervention market, which would be a potential positive for all carotid interventions, including TCAR, no assurance can be provided that this will prove true. In addition, while we believe the higher associated procedural stroke risk for transfemoral carotid artery stenting and steep learning curve will continue to limit the pool of eligible patients and skilled interventionalists, thereby limiting the growth potential for transfemoral CAS in the near term, no assurance can be provided that this will prove true either.

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, Nordson Medical for our balloon catheters, and Galt Medical for our transcarotid access kits. 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, financial condition and results of operations, 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 pandemics, epidemics and other outbreaks, such as COVID-19 and its variants, which may negatively impact our business and operations.

Our business has been in the past and in the future could be adversely impacted by the effects of health pandemics, epidemics and other outbreaks, such as COVID-19 and its variants, including through:

- Postponement of TCAR procedures by physicians or their patients in response or the diversion of resources to treat patients with 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;
- 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, which may translate into fewer than expected TCAR procedures being performed throughout various periods of the pandemic;
- Delays in enrollment in our clinical trials, including our ROADSTER 3 trial, which is related to our standard surgical risk post-approval study;
- Governmental mandates which may impact our personnel and personnel at third-party manufacturing facilities, and the availability or cost of materials, which could disrupt our supply chain and/or reduce our margins;
- 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 an outbreak;
- 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 outbreak 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 the pandemic 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 effect of an outbreak on our anticipated international expansion or regulatory approvals in some countries;
- Hospitals restricting or limiting access for non-patients, including our sales professionals and therapy development specialists, or our sales personnel choosing not to enter hospitals, which could negatively impact our access to physicians and their staff.

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, weakening of economic conditions or consumer confidence and the realization of other risks as described in this section.

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. 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 have differed in the past, and in the future may differ, significantly from our guidance and/or analyst expectations, which has caused in the past and could again cause in the future 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.

Our 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. Analysts and others also publish financial projections or forecasts from time to time. 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 Annual Report on Form 10-K 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 has in the past disappointed and in the future could disappoint investors and analysts and cause the market price of our common stock to decline. While we do not provide quarterly revenue guidance, we lowered our annual revenue guidance in connection with the release of our preliminary third quarter 2023 revenue results in October 2023, which contributed to a significant decrease in our stock price, which has decreased from a 52-week high of $58.04 on January 13, 2023 to a 52-week low of $6.08 on October 26, 2023.

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 Society for Vascular Surgery's Patient Safety Organization and their 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 and currently enrolling patients in 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. 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 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. In addition, the introduction of competitive stents that could be used in TCAR procedures and other products could also put pressure on the pricing of our products. 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. Also, our use of distributors in non-U.S. countries may adversely impact our gross margins.

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, tornados 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 sales training initiatives, to increase or improve 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 continue to hire, train, maintain, motivate and grow our direct sales force could harm our business. Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales force fails to adequately promote, market and sell our products, our revenue may suffer. 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. Because the competition for qualified sales personnel is high, we cannot assure you we will be able to hire and retain sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which could have an adverse impact on our business. In addition, the hiring and training of new sales personnel takes time and could adversely affect our revenue and financial results for a particular period, as could changes in our sales territories and sales structure. 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. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023 and may continue to adversely affect our revenue through the first half of 2024.

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. There is significant competition for direct sales personnel with strong sales skills and clinical knowledge and 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. In addition, the loss of key sales personnel could impact our physician and customer relationships and future ability to sell to certain accounts covered by such personnel. 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.

In addition, 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 or products 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. Competition in our industry has increased with new technologies and market entrants seeking approvals for carotid disease treatment indications in the U.S. 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, Inc., Getinge AB, Baxter International Inc., Terumo Medical Corporation, W.L.Gore and Associates, Inc. and Edwards Lifesciences Corporation. 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 Laboratories, Boston Scientific Corporation, Cook Medical Inc., Cordis Corporation, Medtronic plc, Terumo Medical Corporation, W.L. Gore and Associates, Inc., Contego Medical Inc. and InspireMD, Inc. Preliminary results from Contego Medical Inc.'s PERFORMANCE II and InspireMD, Inc.'s C-Guardians IDE studies were presented at the VIVA conference in November 2023. Abbott Laboratories, Contego Medical Inc. and InspireMD, Inc. have also announced plans to develop products for TCAR. 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 other company stents and not our ENROUTE stent in connection with TCAR procedures, including a recently approved stent by Abbott Laboratories, or 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. This is particularly true in light of the revised NCD 20.7 – Percutaneous Transluminal Angioplasty, which expanded reimbursement coverage of transfemoral carotid artery stenting into asymptomatic and standard surgical risk patients and could lead to increased future competition for our TCAR products.

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 and introduce 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.

Developing products is expensive and time-consuming and could divert management's attention away from our core TCAR products. However, if we are unsuccessful in developing and commercializing new products, our ability to increase our revenue may be impaired. Even if we are successful in developing additional products, the success of any new product offering or enhancements to existing products will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products or product enhancements in a timely but controlled manner;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- be fully FDA-compliant with marketing of new devices or modified products;
- provide adequate training to potential users of our products;
- obtain adequate coverage and reimbursement for our customers performing procedures using our products; and
- develop an effective and dedicated sales and marketing team for any new 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. In addition, we received PMA approval for tapered configurations of our ENROUTE stent in June 2023 and initiated a limited market release in the first quarter of 2024 with a full market release planned in the first half of 2024. If we are unable to continue 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.

In addition, the launch of new products if not timed correctly and if not controlled properly may result in an adverse impact on sales of such new products, as well as sales of our TCAR products. In addition, our new products may not carry the same margins as our current TCAR products, which could adversely affect our gross margins.

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.

Our failure to manage the transition associated with our Chief Executive Officer, retain our existing senior management team, or continue to attract and retain qualified new personnel could have a material adverse effect on 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 our new Chief Executive Officer, or CEO, Charles S. McKhann, our Chief Financial Officer and Chief Operating Officer, Lucas W. Buchanan, and our Chief Commercial Officer, Andrew S. Davis, are essential to driving adoption of our products and revenue growth, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. Mr. McKhann became CEO on November 2, 2023 succeeding Erica J. Rogers, who retired after having served as CEO and on our board of directors for over 11 years. Our failure to manage this CEO change and transition, retain our existing senior management team, or continue to attract and retain qualified new personnel could have a material adverse effect on our business. In addition, the CEO transition and any related uncertainty regarding our future business direction may be disruptive to our business and our relationships with employees and customers. Additionally, the departure of Ms. Rogers as our former CEO resulted in a loss of institutional knowledge and there can be no assurances that we will be able to mitigate that loss through our transitional consulting arrangement with her. If we are unable to execute an orderly transition, our business may be adversely affected. Furthermore, the success of our business is dependent on the continuation of an experienced and talented management team. If we were to lose the benefit of the experience, efforts, and abilities of any of our key executives or members of senior management, our business could be adversely affected. While we implemented retention packages for our key executives and employees during 2023, any of our employees may terminate their employment with us at any time and the recent 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, the significant drop in our stock price during 2023 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.

Our past growth has provided, and our future growth may create, challenges to our organization. The number of our employees has increased significantly during the past several years and in the future, we expect to hire and train new personnel as we continue to grow and expand our operations. 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;
- The total market opportunity for our products and our ability to penetrate and capture market share from other competing products and technologies;
- Our ability to continue to grow our revenues and maintain pricing and gross margins, especially in light of increased competition or investor perception thereof;

- The effect of competing technologies and products on our business, operating results and prospects, or other adverse market developments;
- The scope and timing of investment in and the future success of 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 rate at which we expand internationally and our ability to launch and sell our products successfully in such markets;
- Whether we acquire third-party companies, products or technologies;
- Restructuring, refinancing or repayment of debt;
- 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 impact of health pandemics, epidemics and other outbreaks, such as COVID-19 and its variants, on our business and operations.

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 December 31, 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. Last year's 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 December 31, 2023, 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 Annual Report on Form 10-K, 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 December 31, 2023, our cash equivalents and investments are invested in highly rated money market funds, U.S. treasury bills, 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, 2023, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $332.0 million and $288.6 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 2024. 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, 2023 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 and artificial intelligence, 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 malfunctions, 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 leading-edge cybersecurity solutions, highly-qualified and certified 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 are 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 incur significant costs in an effort to detect and prevent security breaches and incidents, and no assurance can be provided that we will be successful in this regard.

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.

In addition, our IT systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems. This enables us to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the IT needs associated with our evolving products. There can be no assurance that our efforts (including, but not limited to, consolidating, protecting, upgrading, and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology, including, but not limited to, generative artificial intelligence platforms) will be successful or that additional systems issues will not arise in the future.

We have no experience selling our products outside of the United States and may be unsuccessful in achieving adoption of our products and revenue growth outside of the United States in a timely manner or at all. In addition, 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 sell our products outside the United States and increase our international presence. In furtherance of this strategy, we have taken actions to sell our products initially in Japan and China, including but not limited to, securing required regulatory approvals, working towards obtaining reimbursement for our products, and entering into distribution agreements with distributors to sell our products in Japan and China, once we commercially launch our products in those countries. Our future sales in Japan and China, as well as any other country, however, are dependent upon our ability to obtain adequate reimbursement for our products in those countries. If we do not obtain adequate reimbursement for our products in Japan or China or any other country, we may not be successful in selling our products in those countries. In addition, we have no experience selling our products outside the United States and

therefore we may be unsuccessful in achieving adoption of our products and revenue growth outside of the United States in a timely manner or at all. Furthermore, doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations and increases in infrastructure costs including legal, tax, accounting and information technology;
- 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 or enforcing or defending our 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 finding effective and adequately training and managing international distributors;
- Difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established;
- Training of third parties on our products and the procedures in which they are used;
- 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;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- The imposition of additional U.S. and foreign governmental controls or regulations; new or enhanced trade restrictions and restrictions on the activities of foreign agents, representatives, and distributors; withdrawal from or revision to international trade agreements and the imposition or increases in import and export licensing and other compliance requirements, customs duties and tariffs, import and export quotas and other trade restrictions, license obligations, and other non-tariff barriers to trade;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;
- Fluctuations in our operating performance based on our geographic mix of sales;
- Transportation delays and interruptions;
- 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.

In anticipation of our international expansion into Japan and China, we recently entered into exclusive distribution agreements with distributors to sell our products in these countries. Exclusive distribution arrangements, however, involve risk and these distributors and any future distributor we engage may not effectively distribute our products.

Our future sales in Japan and China, once we obtain reimbursement and launch our products in those countries, will depend in large part on the distributors with whom we have entered into exclusive distribution agreements in those countries. While we believe we have selected experienced and qualified distributors in these countries, we will be completely dependent on their efforts to market and sell our products in these countries, and we will be unable to control their efforts completely. In addition, we are unable to ensure that our distributors will comply with all applicable laws regarding the marketing and sale of our products. If our distributors fail to effectively market and sell our products, or comply with all applicable laws, our operating results and business may suffer.

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 2032, unless additional Congressional action is taken.

On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments 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 Japan and China and other countries where we may decide to commercialize could have similar effects.

Effective October 11, 2023, CMS published the final decision memo for NCD 20.7 expanding coverage for CAS, including TCAR, under indication B4 for both high risk and standard surgical risk patients. The revised NCD 20.7 does not impact existing TCAR coverage under indication B3 for FDA-approved post-approval studies such as the VQI TSP. CMS determined that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting, including TCAR, under indication B4 is reasonable and necessary with the placement of an FDA-approved carotid stent and with an FDA-approved or cleared embolic protection device, in patients with symptomatic carotid artery stenosis ≥50% and in patients with asymptomatic carotid artery stenosis ≥70% under the following conditions:

(1) Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS.

(2) First-line evaluation of carotid artery stenosis must use duplex ultrasound.

(3) Computed-tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra-cranial circulation.

(4) Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results or contraindicated for CTA or MRA.

Prior to furnishing CAS, the practitioner must engage in a shared decision-making interaction with the beneficiary, which must include:

(1) Discussion of all treatment options for carotid stenosis, including CEA, CAS (which includes TCAR), and optimal medical therapy (OMT).

(2) Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.

(3) Integration of clinical guidelines (e.g., patient co-morbidities and concomitant treatments).

(4) Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. As a result of the expansion of coverage in NCD 20.7 and CMS's stated goals for broader patient access, we believe there could be rising interest and awareness in minimally invasive carotid stenting procedures including TCAR.

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 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. Analogous foreign law equivalents are more fully described in the section titled "*Business—Government Regulation.*"

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, 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. For example, the FDA issued a final rule in February 2024 replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026. 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. If the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications. 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, PMDA, and NMPA 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.

We are subject to United States and certain foreign laws and regulations relating to export and import controls, sanctions, embargoes, anti-corruption, and anti-money laundering. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which would harm our business.

We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended (FCPA), the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. International trade, tariff, and import/export laws and regulations may require us to obtain licenses or permits in order to complete certain activities necessary for the research, manufacture, and development of our product candidates. Moreover, we expect such laws and regulations, along with associated guidance and interpretations, to evolve over time in ways that may impact various aspects of our business. The process for obtaining any necessary licenses or permits may be lengthy and time-consuming, and if we are not able to obtain any such licenses or permits in a timely manner, we may experience delays in our ability to manufacture, develop, and commercialize our product candidates.

Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, collaborators, and other third parties from authorizing, promising, offering, or providing, directly or indirectly, improper

payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell products, if any, for which we receive regulatory approval outside the United States, to conduct clinical trials, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. In the ordinary course of our business, we may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We may be held liable for the corrupt or other illegal activities of our employees, agents, contractors, collaborators, and other third parties, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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 other international regulatory submissions, 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 may require new 510(k) clearances, premarket approvals, or other international regulatory submissions 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 may require prior FDA approval of a PMA supplement or may require international regulatory activity. 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 or approved 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. Similar requirements for approval of significant changes are in place in international markets. We may not be able to obtain additional 510(k) clearances, premarket approvals, or international 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, PMDA, or NMPA disagree and require 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 Certification Body to maintain ISO 13485:2016 certification of our quality system. 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. The FDA issued a final rule in February 2024 replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026. 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. The FDA conducted an initial facility inspection in our Plymouth, Minnesota location in January 2024 and a one-observation Form 483 Notice of Observation was issued pertaining to a singular piece of production equipment in relation to calibration and preventive maintenance. In response, we initiated a Corrective and Preventive Action, or CAPA, to address the 483.

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, and in October 2023, the State of California adopted broad climate reporting laws that will require certain businesses to report on greenhouse gas (GHG) emissions and climate-related financial risk. Compliance with these climate-related disclosures may result in significant costs and operational impacts 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.

New climate-related reporting rules in California and other jurisdictions could require significant time, attention, and resources from management, and could also lead to increased costs and liabilities.

In March 2022, the SEC proposed new rules that would require public companies to disclose extensive climate-related information in their registration statements and periodic reports. The proposed rules would mandate disclosures related to climate-related risks and their impacts, GHG emissions, and climate-related financial statement metrics. In October 2023, the State of California adopted the Climate Corporate Data Accountability Act and the Climate-Related Financial Risk Act. These broad climate reporting laws that would require certain businesses doing business in California to report on GHG emissions and climate-related financial risks.

As a company that files periodic reports with the SEC and that has operations in California, we may fall under the jurisdiction of these new laws, which impose rigorous reporting obligations regarding our GHG climate-related financial risks and extensive requirements for the disclosure of GHG emissions. Compliance with these climate-related disclosure rules will require substantial time and attention of management and financial resources. We must develop robust systems, processes, and controls for assessing and reporting our climate-related financial risks, as well as ensuring transparency and accuracy in our disclosures.

Risks Related to Ownership of Our Common Stock

The market price of our common stock in the past has been and may continue to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock in the past has been and may continue to be highly volatile and may fluctuate substantially due to many factors, including, without limitation:

- Estimates and recommendations regarding our business, prospects and the value of our common stock by securities analysts, the loss of analyst coverage or our failure to achieve analysts' estimates, which failure to achieve analysts' consensus estimates occurred with both our first quarter 2023 and third quarter 2023 financial results;

- Perceptions by securities analysts and other investors regarding our business, prospects and the value of our common stock, including without limitation, the total market opportunity for our products, our ability to penetrate the market, the effect of the revised NCD 20.7 and the effect on our business and results of operations, including without limitation pricing, of competitive stents and products;

- 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 and other factors, such as pricing and the effect of stocking orders if we sell to international distributors;

- The financial and business projections we may provide to the public, any changes in these projections or our failure to meet these projections, which occurred when we revised downward our annual revenue guidance in October 2023;

- 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, the impact of GLP-1 usage, geopolitical tensions including the war between Russia and Ukraine, the war between Israel and Hamas and changes in China-Taiwan relations;

- Changes in reimbursement by current or potential payers, including CMS's final decision on NCD 20.7, Percutaneous Transluminal Angioplasty, that provides coverage for CAS including 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, such as the recent retirement of our prior CEO and appointment of a new CEO;

- Product recalls, backorders or other problems associated with our products;

- Our ability to obtain required approvals and reimbursement coverage for our products internationally and successfully launch and sell our products in such markets;

- 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;

- Developments in our industry; and

- Other risks and uncertainties described in this report.

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, especially significant drops in stock price like we have recently experienced. Such litigation 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 control over financial reporting and any failure to maintain the adequacy of our 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 public 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 restated certificate of incorporation and amended and restated bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

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

- 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 restated certificate of incorporation and amended and restated bylaws;
- The right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- 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 restated certificate of incorporation and amended and restated 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 restated certificate of incorporation and amended and restated 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. The recent significant drop in our stock price makes us particularly vulnerable to activist investors at this time.

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 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Background

Cybersecurity, compliance, data privacy, and data protection are essential to our business. In the ordinary course of business, we collect and store certain confidential information, such as the specifications of our products, information about our employees, customers, contractors, vendors, and suppliers, and information about TCAR procedures, which in some instances may include identifiable patient information. To safeguard this information, we have implemented a cybersecurity defense-in-depth approach leveraging the Center for Internet Security, Inc. (CIS) Critical Security Controls (CSC) framework designed to identify, meet, and defeat dangerous cyber attacks in order to protect confidential information, mitigate data compromise and breaches, and provide IT resiliency. The CIS CSC framework defines five critical areas to build robust cybersecurity defense posture. We have developed and maintain a collection of policies and procedures to implement and support this cybersecurity framework.

Role of Management and Board Oversight

Our cybersecurity team is comprised of individuals with experience in cybersecurity who hold cybersecurity-specific credentials and certifications. The team members belong to relevant professional organizations and receive continuing education and certification to stay abreast of emerging trends and cybersecurity best practices.

We have established a Technology Steering Committee, or TSC, containing members of our senior management team to provide governance and strategic direction for managing cyber risks, maintaining IT regulatory compliance, and optimizing technology initiatives for alignment with our company goals and objectives. The TSC convenes quarterly, and meetings include updates on cybersecurity matters provided by the cybersecurity leader.

Our board of directors has delegated to the audit committee, which is comprised of entirely independent directors, the responsibility to oversee our cybersecurity programs and cyber-related risks. Specifically, audit committee delegation under its formal written charter includes the responsibility to oversee the integrity of our IT systems, processes and data, and review and assessment with management (i) the adequacy of controls and security for our IT systems, processes and data, and (ii) our contingency plans in the event of a breakdown or security breach affecting our IT systems.

The cybersecurity team reports to our Chief Accounting Officer, which in turn reports to our Chief Financial Officer. Both officers regularly attend audit committee meetings where cybersecurity is discussed and the audit committee is updated on security risks and key initiatives at least twice per year by the senior management team. The TSC is responsible for providing cybersecurity risk management oversight and approving the budget to fund our IT and cybersecurity programs. An important purpose of these management updates is to inform the audit committee of any potential risks and remediation tactics related to our cybersecurity posture, IT systems, and data privacy.

Use of Consultants and Advisors

We engage with a range of external experts, including cybersecurity assessors, consultants, auditors, and legal counsel in evaluating and testing our risk management systems. This enables us to leverage specialized knowledge and insights, ensuring our cybersecurity strategies and processes remain current.

We have engaged a managed security services company to provide 24x7x365 monitoring to detect cyber threats and support us in containing and responding to cyber threats. The services provided by the managed security services company include monitoring for and updating us regarding emerging cybersecurity threats, real-time monitoring of our firewalls and other security controls, and support for the development and execution of our Incident Response Plan. The managed security services company performs monthly vulnerability scanning and generates reports. Our cybersecurity team has access to dashboards providing status updates on the managed security services company's cybersecurity-related activity, meets regularly with the managed security services company's staff, and receives regular reporting from the managed security services company.

We also receive and participate in other third-party cybersecurity assessments, such as: quarterly vulnerability scanning as part of our PCI DSS compliance requirements, annual network assessments, annual penetration testing, and vulnerability scans as part of our cyber insurance underwriting process.

In addition, we engage specialized consultants and third-party managed service providers on a project-specific basis to assist us with projects that will improve our IT infrastructure, strengthen our security posture, and improve our cyber readiness.

Cybersecurity Strategy and Risk Management

We have integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity risk management. This integration ensures that cybersecurity considerations are an integral part of our decision-making processes at every level. Our cybersecurity program is designed for assessing, identifying and managing material risks from cybersecurity threats to the confidentiality, integrity, and availability of our assets and information. Risk management is embedded into our IT processes and we continuously monitor risk by evaluating emerging threats and vulnerabilities.

We have established security controls based on the CIS CSC framework. Key components of our cybersecurity program include, but are not limited to, asset management, encryption, data loss prevention technology, access controls, multi-factor authentication, vulnerability management, independent penetration testing, email and web gateway protection, multi-faceted backup and data recovery solutions, anti-malware, firewalls, IDS and IPS, auditing and monitoring, regular policy updates, security awareness training, anti-phishing campaigns, and third-party risk management. We also

subscribe to third-party threat intelligence tools and services that support monitoring, analyzing, and responding to emerging risks and threats.

We have established an Incident Response Plan and a Security Operations Center to manage any cyber incident. We have retained a third-party incident response firm to support incident detection, management, and mitigation. We also maintain appropriate levels of cyber insurance. We implement processes to oversee and manage the risks associated with third-party service providers. We conduct security assessments of critical third-party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards. The monitoring includes ongoing assessments by our Information Security team. This approach is designed to mitigate risks related to data breaches or other security incidents originating from third parties.

At least annually, we conduct information security awareness training for all employees. In addition, we have retained a third-party vendor to provide regular online awareness training modules for our employees. Each module contains a video extract followed by a short quiz.

To date, we have not experienced any material security incidents or data breaches as a result of a compromise of our information systems and are not aware of any cybersecurity incidents that have had a material impact or are reasonably likely to materially affect our business strategy, operating results, or financial condition.

Item 2. Properties

We currently lease approximately 31,000 square feet for our corporate headquarters and manufacturing facility located in Sunnyvale, California under a lease agreement which terminates in October 2027. We have an additional option to extend the lease term for a period of five years. The option must be exercised no more than 12 months and no less than nine months prior to the expiration of the applicable term.

We also lease approximately 82,000 square feet of office and manufacturing space located in Plymouth, Minnesota under a lease agreement which terminates in November 2029. We have the option to extend the lease term for two additional five-year periods. The option must be exercised no more than 12 months and no less than nine months prior to the expiration of the applicable term. We believe our two facilities meet our current and future anticipated needs.

Item 3. Legal Proceedings

We are subject to litigation and other legal actions from time to time arising in the ordinary course of business, including intellectual property, products liability, breach of contract, commercial, employment, and other similar claims which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. In the opinion of management, the outcome of these and any other pending legal matters will not have a material adverse effect on our financial condition, results of operations or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed on The Nasdaq Global Select Market under the symbol “SILK,” and began trading on April 4, 2019. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of January 31, 2024, there were approximately 54 stockholders of record of our common stock. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our term loan agreement limits our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions.

Recent Sales of Unregistered Securities

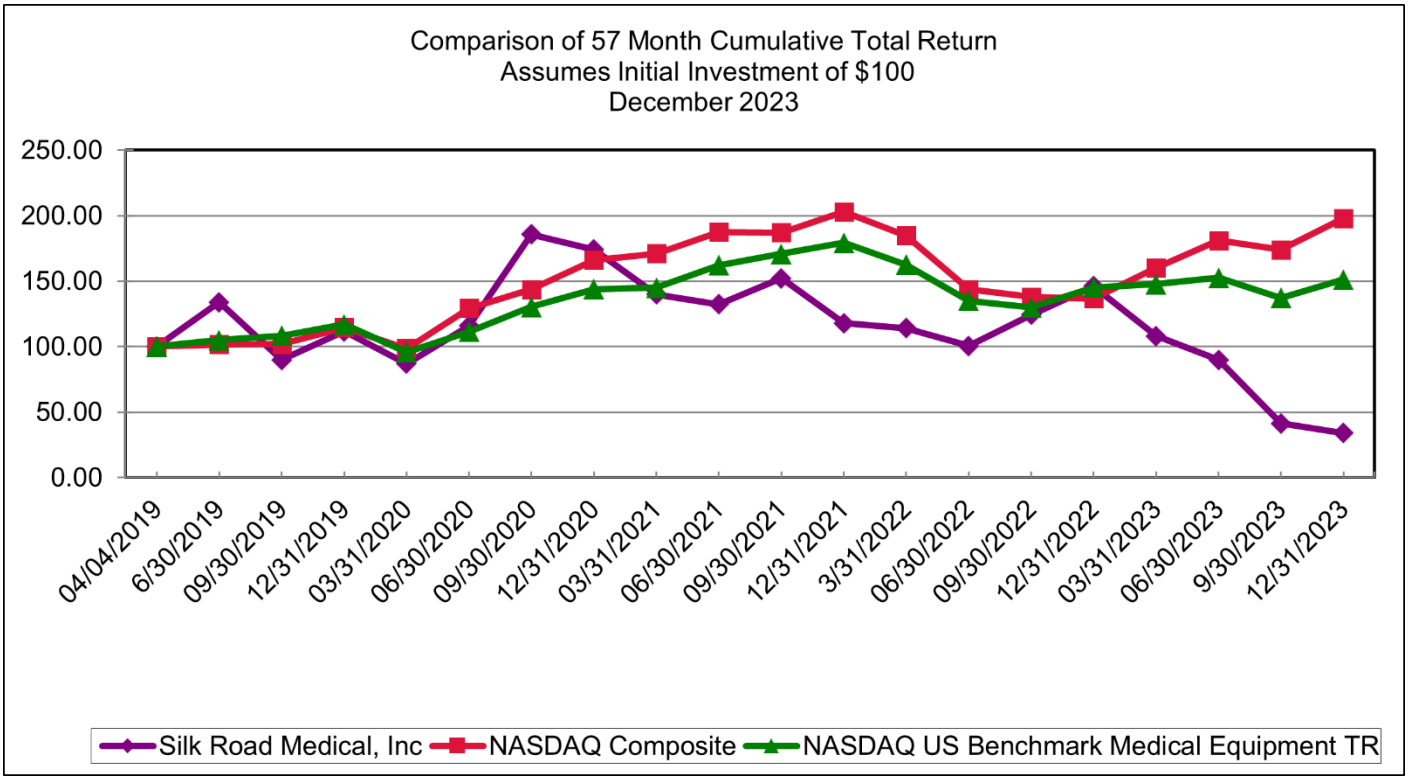
We did not sell any unregistered shares of our common stock or other equity securities of ours during the quarter ended December 31, 2023.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the quarter ended December 31, 2023.

Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock with the total return for (i) the Nasdaq Composite Index (U.S.) and (ii) the Nasdaq U.S. Benchmark Medical Equipment TR Index for the period from April 4, 2019 (the first day of trading of our common stock), through December 31, 2023. The graph assumes an investment of $100 in our common stock at market close on April 4, 2019 and the reinvestment of dividends, if any. The comparisons in the table are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



$100 investment in stock or index	Apr. 4, 2019	Jun. 30, 2019	Sep. 30, 2019	Dec. 31, 2019	Mar. 31, 2020	Jun. 30, 2020	Sep. 30, 2020	Dec. 31, 2020	Mar. 31, 2021	Jun. 30, 2021	Sep. 30, 2021	Dec. 31, 2021	Mar. 31, 2022	Jun. 30, 2022	Sep. 30, 2022	Dec. 31, 2022	Mar. 31, 2023	Jun. 30, 2023	Sep. 30, 2023	Dec. 31, 2023
Silk Road Medical, Inc. (SILK)	$ 100	$ 134	$ 90	$ 112	$ 87	$ 116	$ 186	$ 174	$ 140	$ 132	$ 152	$ 118	$ 114	$ 101	$ 124	$ 146	$ 108	$ 90	$ 41	$ 34
Nasdaq Composite	$ 100	$ 102	$ 102	$ 115	$ 99	$ 129	$ 144	$ 166	$ 171	$ 188	$ 187	$ 203	$ 185	$ 144	$ 138	$ 137	$ 160	$ 181	$ 174	$ 198
Nasdaq US Benchmark Medical Equipment TR	$ 100	$ 105	$ 108	$ 117	$ 96	$ 112	$ 130	$ 144	$ 145	$ 162	$ 171	$ 179	$ 163	$ 135	$ 130	$ 145	$ 148	$ 153	$ 137	$ 151

Item 6. [Reserved]

Item 7. Management's 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 audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K 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 Annual Report on Form 10-K entitled "Risk Factors" and the "Cautionary Note Regarding Forward-Looking Statements" beginning on page 1.

This section of this Annual Report on Form 10-K generally discusses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

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 expanded our product portfolio with the full market release of our ENROUTE Enflate Transcarotid RX Balloon Dilation Catheter in the second quarter of 2023. Also in the second quarter of 2023, we received 510(k) clearance for our next generation neuroprotection system, or ENROUTE NPS PLUS, which is designed to support additional ease-of-use and further minimize the risk for complications. We are planning for the upcoming launch of our ENROUTE NPS PLUS in the first half of 2024. We also received PMA approval for tapered configurations of our ENROUTE stent in the second quarter of 2023, which provides greater choice for physicians to address the diversity of patient specific anatomy. We initiated a limited market release in the first quarter of 2024 with a full market release planned in the first half of 2024. As of December 31, 2023, more than 85,000 TCAR procedures have been performed globally, including more than 25,000 in the United States during 2023.

Products for 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. A final decision memo was released on October 11, 2023. In the final decision memo, CMS determined that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting is reasonable and necessary with the placement of an 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% under the following conditions:

- Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS;
- First-line evaluation of carotid artery stenosis must use duplex ultrasound;
- Computed-tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra-cranial circulation; and
- Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results or contraindicated for CTA or MRA.

Prior to furnishing CAS, the practitioner must engage in a shared decision-making interaction with the beneficiary, which must include:

- Discussion of all treatment options for carotid stenosis, including CEA, CAS (which includes TCAR), and optimal medical therapy (OMT);
- Explanation of risks and benefits for each option specific to the beneficiary's clinical condition;
- Integration of clinical guidelines (e.g., patient co-morbidities and concomitant treatments); and
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. As a result of the expansion of coverage in NCD 20.7 and CMS's stated goals for broader patient access, we believe there could be rising interest and awareness in minimally invasive carotid stenting procedures including TCAR.

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 CEA or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. We consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. 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. During 2023, we expanded our sales and marketing infrastructure, including a number of sales personnel and sales territories, to help us drive and support revenue growth. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023 and may continue to adversely affect our revenue through the first half of 2024.

While we do not currently sell our products in markets outside the United States, we have obtained some and are pursuing additional regulatory approvals and commercial partners for selling certain of our products 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 we submitted for Shonin approval for the ENROUTE NPS PLUS in the second quarter of 2023. During the fourth quarter of 2023, we entered into a distribution agreement for our products in Japan, and are pursuing next steps including assessing the reimbursement process and our pathway and timeline to launch in Japan. In China, in the first quarter of 2023, we received approval from China's NMPA for our ENROUTE NPS. During the first quarter of 2024 we received approval from China's NMPA for our ENROUTE stent, and we also entered into a distribution agreement for our products in China. We expect to submit our ENROUTE NPS PLUS for NMPA approval during the first quarter of 2024.

We manufacture and distribute the ENROUTE NPS and ENROUTE NPS PLUS at our facilities in Sunnyvale, California, and Plymouth, Minnesota using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We believe our combined facilities will be sufficient to meet our manufacturing needs for at least the next five years. We purchase our other products, including our ENROUTE stent and ENROUTE Enflate product, from third-party contract manufacturers. Many of our third-party manufacturers and outside vendors are currently single-source suppliers. We remain concerned with the ability of a critical supplier of certain polymer tubing materials, and related components used in our products to provide us and 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 customer.

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 years ended December 31, 2023 and 2022. Key performance indicators that drive our revenue include the number of procedures, 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. However, any decreases in our key performance indicators could have a negative impact on our future revenue, as could other factors, such as 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, and increased competition. In addition, we have expanded our sales and marketing infrastructure, including a number of sales personnel and sales territories, to help us drive and support revenue growth and we intend to continue this expansion. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023, we expect this may continue to adversely affect our revenue through the first half of 2024.

Our revenue has fluctuated and we expect to continue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality and number of selling days. With respect to seasonality, our first quarter revenue may be harmed by adverse weather and the 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 may adversely affect procedure volumes that in turn affect hospital ordering patterns. In addition, we have also experienced moderate procedure volumes 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 and ENROUTE NPS PLUS 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 have and may continue to experience 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 continue to be slightly lower 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 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 impact our product development efforts and clinical and regulatory matters for the foreseeable future. COVID-19 has impacted 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.

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 is offset by interest income earned on our cash, cash equivalents and investments.

Results of Operations:

(in thousands, except percentages)	Year Ended December 31,			
	2023	2022	Change	% Change
Revenue	$ 177,134	$ 138,638	$ 38,496	28%
Cost of goods sold	50,048	37,876	12,172	32%
Gross profit	127,086	100,762	26,324	26%
Operating expenses:				
Research and development	41,324	36,449	4,875	13%
Selling, general and administrative	145,033	116,317	28,716	25%
Total operating expenses	186,357	152,766	33,591	22%
Loss from operations	(59,271)	(52,004)	(7,267)	14%
Interest income (expense), net	3,086	(2,571)	5,657	220%
Loss on debt extinguishment	—	(245)	245	100%
Other income (expense), net	442	(190)	632	333%
Net loss	$ (55,743)	$ (55,010)	$ (733)	1%

Comparison of Years Ended December 31, 2023 and 2022

Revenue. Revenue increased $38.5 million, or 28%, to $177.1 million during the year ended December 31, 2023, compared to $138.6 million during the year ended December 31, 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 as compared with the prior year period, it was impacted by the natural sales disruption resulting from the expansion of our sales and marketing infrastructure during 2023.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $12.2 million, or 32%, to $50.0 million during the year ended December 31, 2023, compared to $37.9 million during the year ended December 31, 2022. This increase was attributable to the increase in the number of products sold. Gross margin for the year ended December 31, 2023 decreased to 72%, compared to 73% for the year ended December 31, 2022. The decrease in gross margin during 2023 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 for most of the prior year period. Gross margin for 2022 was adversely affected by COVID-19 related production issues in the first quarter of 2022.

Research and Development Expenses. R&D expenses increased $4.9 million, or 13%, to $41.3 million during the year ended December 31, 2023, compared to $36.4 million during the year ended December 31, 2022. This was driven primarily by growth in personnel and investment in new and ongoing R&D programs and specifically by an increase of $4.3 million in personnel-related expenses, including stock-based compensation, as a result of increased headcount, an increase of $0.8 million in clinical and regulatory expenses, and an increase of $0.4 million related to product development materials. This increase was partially offset by a decrease in outside services fees.

Selling, General and Administrative Expenses. SG&A expenses increased $28.7 million, or 25%, to $145.0 million during the year ended December 31, 2023, compared to $116.3 million during the year ended December 31, 2022. This increase was primarily due to the continued expansion of our sales team and commercial efforts, compared to the prior year period. More specifically, the increase is attributable to an increase of $24.8 million in payroll and personnel-related expenses, an increase of $1.5 million in consulting and professional fees, a net increase of $1.2 million in physician training and travel-related costs, an increase of $0.7 million in software-related costs, and an increase of $0.5 million in the allocated costs of facilities and other related expenses. Personnel-related expenses included stock-based compensation expense of $29.6 million and $18.6 million for the years ended December 31, 2023 and 2022, respectively.

Interest Income (Expense), Net. Interest income (expense), net increased $5.7 million, or 220%, to income of $3.1 million during the year ended December 31, 2023, compared to an expense of $2.6 million during the year ended December 31, 2022. The increase in net interest income was attributable to higher average 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 increased to income of $0.4 million during the year ended December 31, 2023, compared to an expense of $0.2 million during the year ended December 31, 2022. The increase in net other income was attributable to $0.6 million in other income received under a government grant and job creation fund, partially offset by losses on the disposal of property and equipment during the year.

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 December 31, 2023, we had cash, cash equivalents and investments of $190.9 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 available under a loan agreement, as described in more detail below.

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 the future sale of our products 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 the financial statements contained in this report. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of TCAR and our products;
- The total market opportunity for our products and our ability to penetrate and capture market share from other competing products and technologies;

- Our ability to continue to grow our revenues and maintain pricing and gross margins, especially in light of increased competition or investor perception thereof;
- The effect of competing technologies and products on our business, operating results and prospects, or other adverse market developments;
- The scope and timing of investment in and the future success of 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 rate at which we expand internationally and our ability to launch and sell our products successfully in such markets;
- Whether we acquire third-party companies, products or technologies;
- Restructuring, refinancing or repayment of debt;
- The costs associated with any future product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights; and
- The impact of health pandemics, epidemics and other outbreaks, such as COVID-19 and its variants, on our business and operations.

Loan Agreement

On May 27, 2022, we entered into a Loan and Security Agreement, or Loan Agreement, with Oxford Finance LLC and its agent, or 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. As of December 31, 2023, there were no amounts outstanding under the $25.0 million secured revolving credit facility.

The term loans and any revolving loans mature on May 1, 2027. 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 the 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. To date, we have not exercised this option. If we exercise this option, then the maturity date for both the revolving loans and the term loans will be May 1, 2028. The principal amount of outstanding revolving loans, together with accrued and unpaid interest, is due on the maturity date.

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 December 31, 2023, the aggregate outstanding principal balance under the term loan facility was $75.0 million 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. The term loan may not be reborrowed once repaid, but we may prepay the term loan at any time in full, or in part in increments of $10.0 million. We are 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, we are 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 we exercise our option to extend the amortization date and maturity date. We are also obligated to pay other customary fees for a loan facility of this size and type.

Our obligations under the Loan Agreement are secured by substantially all of our assets. The Loan Agreement requires that we 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, we 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 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 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 our 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 December 31, 2023, the aggregate outstanding principal balance under the Loan Agreement was $75.0 million and the variable interest rate was 7.5%. As of December 31, 2023, we were in compliance with all covenants under the term loan agreement.

Material Cash Requirements

Our material cash requirements include our outstanding term loan under the Loan Agreement, operating leases and non-cancellable purchase commitments. As of December 31, 2023, we had principal, interest and fees commitments of $95.9 million under the Loan Agreement, of which $5.9 million in interest and fees is expected to be paid within the next 12 months. Our operating lease commitments consist of our lease obligations for our facilities in Sunnyvale, California and Plymouth, Minnesota. Our total operating lease commitments as of December 31, 2023 are approximately $10.8 million, of which $2.0 million is expected to be paid within the next 12 months. We have non-cancellable purchase commitments primarily related to our ENROUTE stent, as described under "Cordis Supply Agreement" below and other inventory components of approximately $14.4 million within the next 12 months.

Cordis License Agreement

We have paid Cordis a one-time license execution fee and are obligated to pay royalties to Cordis on a calendar quarter basis during the term of the Cordis License Agreement, calculated based on net sales of the licensed products we sell during the preceding quarterly period. The license granted under Cordis License Agreement shall remain in full force and effect unless terminated by mutual agreement between us and Cordis.

Cordis Supply Agreement

We are obligated under the Cordis Supply Agreement to purchase a minimum volume of the ENROUTE stent annually. This obligation is binding during the term of the Cordis Supply Agreement.

Cash Flows

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

(in thousands)	Year Ended December 31, 2023	2022	2021
Net cash (used in) provided by:			
Operating activities	$ (32,014)	$ (32,581)	$ (38,935)
Investing activities	(7,176)	(162,068)	72,644
Financing activities	3,887	139,699	6,978
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (35,303)	$ (54,950)	$ 40,687

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $32.0 million, consisting primarily of a net loss of $55.7 million and an increase in net operating assets of $13.9 million, partially offset by non-cash charges of $37.6 million. The change in net operating assets was primarily due to increases in accounts receivable, due to an increase in sales, in inventories, to support the growth of our operations, prepaid expenses and other current assets, and an increase in accounts payable and accrued liabilities due to the timing of payments and the growth of our operations and accrued payroll and related expenses. The non-cash charges primarily consisted of stock-based compensation, as well as depreciation and amortization, accretion of discounts on investments, amortization of right-of-use assets, non-cash interest expense, provision for excess and obsolete inventories, and a loss on the disposal of property and equipment.

Net cash used in operating activities for the year ended December 31, 2022 was $32.6 million, consisting primarily of a net loss of $55.0 million and an increase in net operating assets of $6.0 million, partially offset by non-cash charges of $28.4 million. The increase in net operating assets was primarily due to increases in accounts receivable due to an increase in sales and in inventories to support the growth of our operations and a decrease in other liabilities due to the timing of payments. These changes were partially offset by increases in accounts payable and accrued liabilities, due to the timing of payments and the growth of our operations and accrued payroll and related expenses. 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, accretion of discounts on investments, loss on debt extinguishment and a loss on the disposal of property and equipment. We recognized a loss on debt extinguishment of $0.2 million in connection with the early termination of our prior term loan agreement with Stifel Bank.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities in the year ended December 31, 2023 was $7.2 million, which consisted of purchases of investments of $175.0 million and purchases of property and equipment of $1.5 million, partially offset by proceeds from maturities of investments of $169.3 million.

Net cash used in investing activities in the year ended December 31, 2022 was $162.1 million, which consisted of purchases of investments of $168.2 million and purchases of property and equipment of $5.0 million, partially offset by proceeds from maturities of investments of $11.1 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the year ended December 31, 2023 was $3.9 million, which reflects proceeds from stock option exercises and purchases under our employee stock purchase plan.

Net cash provided by financing activities in the year ended December 31, 2022 was $139.7 million, which reflects net proceeds of $109.0 million from our October 2022 public offering and net proceeds of $73.9 million from the issuance of debt, partially offset by repayment of debt of $49.0 million and proceeds from stock option exercises and purchases under our employee stock purchase plan of $5.8 million.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for

making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our audited financial statements included in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policy, which is most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

Our revenue is generated from the sale of our products to hospitals and medical centers in the United States through direct sales representatives and is primarily comprised of product revenue net of returns, administration fees and sales rebates. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of our products to customers, either upon shipment of the product or delivery of the product to the customer under our standard terms and conditions. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring the goods. We accept product returns at our discretion or if the product is defective as manufactured. We establish estimated provisions for returns based on historical experience and consideration of other factors that we believe could significantly impact our expected returns.

Recently Issued Accounting Pronouncements

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

Item 7A. 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

Our exposure to market risk is principally confined to our cash, cash equivalents and investments and our outstanding variable-rate term debt, capped at the maximum rate of 7.50%.

We had cash, cash equivalents and investments of $190.9 million as of December 31, 2023, which consisted of bank deposits, money market funds, U.S. government securities, U.S. treasury bills, 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. We place our cash, cash equivalents, and investments with high-quality financial institutions and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. 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 December 31, 2023. While we believe our cash, cash equivalents, and investments do not contain excessive risk, we cannot provide absolute assurance that, in the future, our investments will not be subject to adverse changes in market value.

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 December 31, 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 December 31, 2023 and 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 the financial statements included in this report, we have not experienced any losses on our deposits and all of our cash deposited with SVB has been accessible to us. Given the continued potential instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

As of December 31, 2023, our cash equivalents and investments are invested in highly rated money market funds, U.S. treasury bills, 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 December 31, 2023 or 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 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Silk Road Medical, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheets of Silk Road Medical, Inc. (the "Company") as of December 31, 2023 and 2022, and the related statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2023, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2023 appearing under Item 15(b) (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become

inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition

As described in Note 2 to the financial statements, 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 total revenue was $177.1 million for the year ended December 31, 2023. Revenue is measured as the amount of consideration management expects to receive in exchange for transferring the goods.

The principal consideration for our determination that performing procedures relating to revenue recognition is a critical audit matter is the significant audit effort in performing procedures related to the accuracy and occurrence of revenue transactions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the recording of product sales upon shipment of the product or delivery of the product to the customer. These procedures also included, among others, (i) testing revenue transactions by evaluating the settlement of invoices and credit memos, ii) evaluating credit memos issued during the year, iii) tracing transactions not settled to a detailed listing of accounts receivable; iv) confirming a sample of outstanding customer invoice balances at year end and, for confirmations not returned, obtaining and inspecting source documents, including purchase orders, invoices, sales contracts, proof of delivery, and subsequent cash receipts, where applicable, and v) testing the completeness and accuracy of data provided by management.

/s/ PricewaterhouseCoopers LLP
Minneapolis, Minnesota
February 28, 2024

We have served as the Company's auditor since 2013.

Silk Road Medical, Inc.
Balance Sheets

(in thousands, except share and per share data)	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 20,210	$ 55,358
Short-term investments	161,264	158,316
Accounts receivable, net of allowances of $26 and $3 at December 31, 2023 and December 31, 2022, respectively	23,573	18,007
Inventories	29,876	19,293
Prepaid expenses and other current assets	5,912	3,924
Total current assets	240,835	254,898
Long-term investments	9,456	—
Property and equipment, net	8,114	9,372
Restricted cash	—	155
Other non-current assets	6,904	5,260
Total assets	$ 265,309	$ 269,685
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,676	$ 2,523
Accrued liabilities	24,607	21,965
Total current liabilities	30,283	24,488
Long-term debt	75,626	74,596
Other liabilities	8,249	6,726
Total liabilities	114,158	105,810
Commitments and contingencies (Note 7)	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 at December 31, 2023 and 2022		
Shares issued and outstanding: none at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value		
Shares authorized: 100,000,000 at December 31, 2023 and 2022		
Shares issued and outstanding: 39,165,481 and 38,355,972 at December 31, 2023 and 2022, respectively	39	38
Additional paid-in capital	550,495	507,715
Accumulated other comprehensive income (loss)	72	(166)
Accumulated deficit	(399,455)	(343,712)
Total stockholders' equity	151,151	163,875
Total liabilities and stockholders' equity	$ 265,309	$ 269,685

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

Silk Road Medical, Inc.
Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)	Year Ended December 31,		
	2023	2022	2021
Revenue	$ 177,134	$ 138,638	$ 101,475
Cost of goods sold	50,048	37,876	25,446
Gross profit	127,086	100,762	76,029
Operating expenses:			
Research and development	41,324	36,449	27,110
Selling, general and administrative	145,033	116,317	96,387
Total operating expenses	186,357	152,766	123,497
Loss from operations	(59,271)	(52,004)	(47,468)
Interest income	9,957	2,527	198
Interest expense	(6,871)	(5,098)	(2,518)
Loss on debt extinguishment	—	(245)	—
Other income (expense), net	442	(190)	(23)
Net loss	(55,743)	(55,010)	(49,811)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net	238	(166)	(39)
Other comprehensive income (loss)	238	(166)	(39)
Comprehensive loss	$ (55,505)	$ (55,176)	$ (49,850)
Net loss per share, basic and diluted	$ (1.44)	$ (1.54)	$ (1.44)
Weighted average common shares used to compute net loss per share, basic and diluted	38,804,343	35,775,672	34,635,358

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

Silk Road Medical, Inc.
Statements of Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Paid-in Capital	Deficit	Income (Loss)	Total
Balances at December 31, 2020	34,249,649	$ 34	$ 346,318	$ (238,891)	$ 39	$ 107,500
Exercise of stock options	643,507	1	4,841	—	—	4,842
Issuance of common stock upon vesting of restricted stock units	34,964	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	52,776	—	2,104	—	—	2,104
Stock-based compensation	—	—	14,612	—	—	14,612
Disgorgement of short-swing profits, net	—	—	32	—	—	32
Net loss	—	—	—	(49,811)	—	(49,811)
Change in unrealized loss on investments, net	—	—	—	—	(39)	(39)
Balances at December 31, 2021	34,980,896	35	367,907	(288,702)	—	79,240
Issuance of common stock in connection with public offering, net of underwriting discount, commissions and offering costs of $6,008	2,674,419	3	108,989	—	—	108,992
Exercise of stock options	453,199	—	3,364	—	—	3,364
Issuance of common stock upon vesting of restricted stock units	148,239	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	99,219	—	2,432	—	—	2,432
Stock-based compensation	—	—	25,023	—	—	25,023
Net loss	—	—	—	(55,010)	—	(55,010)
Change in unrealized loss on investments, net	—	—	—	—	(166)	(166)
Balances at December 31, 2022	38,355,972	38	507,715	(343,712)	(166)	163,875
Exercise of stock options	199,642	—	1,486	—	—	1,486
Issuance of common stock upon vesting of restricted stock units	410,085	1	—	—	—	1
Issuance of common stock under employee stock purchase plan	199,782	—	2,401	—	—	2,401
Stock-based compensation	—	—	38,893	—	—	38,893
Net loss	—	—	—	(55,743)	—	(55,743)
Change in unrealized gain on investments, net	—	—	—	—	238	238
Balances at December 31, 2023	39,165,481	$ 39	$ 550,495	$ (399,455)	$ 72	$ 151,151

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

Silk Road Medical, Inc.
Statements of Cash Flows

(in thousands)	Year Ended December 31,		
	2023	2022	2021
Cash flows from operating activities			
Net loss	$ (55,743)	$ (55,010)	$ (49,811)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	2,696	2,127	1,032
Stock-based compensation expense	38,893	25,023	14,612
Amortization of premiums (accretion of discounts) on investments, net	(6,497)	(1,419)	577
Amortization of debt discount and debt issuance costs	232	218	158
Amortization of right-of-use asset	1,096	1,041	887
Non-cash interest expense	819	1,037	—
Loss on extinguishment of debt	—	245	—
Loss on disposal of property and equipment	160	180	9
Provision for (recovery of) doubtful accounts receivable	45	(3)	6
Provision for excess and obsolete inventories	198	6	77
Changes in operating assets and liabilities:			
Accounts receivable	(5,610)	(6,172)	(2,769)
Inventories	(10,781)	(1,447)	(5,563)
Prepaid expenses and other current assets	(1,988)	(525)	(772)
Other assets	(236)	(27)	(117)
Accounts payable	3,063	967	(1,159)
Accrued liabilities	2,854	1,868	4,418
Other liabilities	(1,215)	(690)	(520)
Net cash used in operating activities	(32,014)	(32,581)	(38,935)
Cash flows from investing activities			
Purchases of property and equipment	(1,507)	(5,005)	(4,758)
Proceeds from sale of property and equipment	—	—	2
Purchases of investments	(174,969)	(168,163)	—
Proceeds from maturity of investments	169,300	11,100	77,400
Net cash provided by (used in) investing activities	(7,176)	(162,068)	72,644
Cash flows from financing activities			
Proceeds from public offerings, net of underwriting discount, commissions and offering costs paid	—	108,992	—
Proceeds from long-term debt, net	—	73,911	—
Proceeds from issuance of common stock	3,887	5,796	6,946
Principal repayment of long-term debt	—	(49,000)	—
Proceeds from disgorgement of short-swing profits, net	—	—	32
Net cash provided by financing activities	3,887	139,699	6,978
Net change in cash, cash equivalents and restricted cash	(35,303)	(54,950)	40,687
Cash, cash equivalents and restricted cash, beginning of year	55,513	110,463	69,776
Cash, cash equivalents and restricted cash, end of year	$ 20,210	$ 55,513	$ 110,463
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 5,821	$ 3,843	$ 2,360
Noncash investing and financing activities:			
Accounts payable and accrued liabilities for purchases of property and equipment	$ 67	$ 117	$ 1,138
Right-of-use asset obtained in exchange for lease obligation	$ 2,504	$ 903	$ 3,307

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

1. Formation and Business of the Company

The Company

Silk Road Medical, Inc., or the Company, was incorporated in the state of Delaware on March 21, 2007. The Company, has developed a technologically advanced, minimally-invasive solution for patients with carotid artery disease who are at risk for stroke. The Company's portfolio of 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. The Company commercialized its products in the United States beginning in late 2015.

Liquidity

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2023, the Company had an accumulated deficit of $399,455,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents and available-for-sale securities of $190,930,000 as of December 31, 2023, as well as its expected revenues will provide sufficient funds to allow the Company to fund its planned current operations for the next 12 months from the issuance of these financial statements.

Public Offering

In October 2022, the Company completed an underwritten public offering of 2,674,419 shares of its common stock at a public offering price of $43.00 per share. The shares include the full exercise of the underwriters' option to purchase an additional 348,837 shares pursuant to the underwriting agreement. The Company received cash proceeds of approximately $108,992,000 after deducting underwriting discounts and commissions of approximately $5,750,000 and expenses of approximately $258,000.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America, or U.S. GAAP.

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 December 31, 2023 and 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

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

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same amounts shown in the statements of cash flows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	$ 20,210	$ 55,358
Restricted cash	—	155
Total cash, cash equivalents and restricted cash	$ 20,210	$ 55,513

The Company had no restricted cash as of December 31, 2023. 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.

Investments

Short-term and long-term investments consist of debt securities classified as available-for-sale. Short-term investments 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 years ended December 31, 2023, 2022 and 2021. 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 years ended December 31, 2023, 2022 or 2021 and there were no impairment charges for unrealized losses in the periods presented.

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 years ended December 31, 2023, 2022 and 2021.

As of December 31, 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 December 31, 2023 and 2022, no customer represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2023, 2022 and 2021, 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 finished goods, components and sub-assemblies continue to be manufactured by sole suppliers, the most significant of which is the ENROUTE Transcarotid Stent System, manufactured by Cordis Corporation, or Cordis. Disruption in finished goods, 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, competition, 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.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company estimates allowances for expected credit losses. Specifically, the Company makes estimates on the collectability of customer accounts based primarily on analysis of historical trends and experience and changes in customers' financial condition. The Company uses its judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. These specific allowances are reevaluated and adjusted as additional information is received that impacts the amount reserved. During the years ended December 31, 2023, 2022 and 2021, the Company did not experience any material credit-related losses.

Inventories

Inventories are valued at the lower of cost to purchase or manufacture the inventory or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life prior to sale to record a provision for excess and obsolete inventory when appropriate. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of goods sold.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation or amortization. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, typically three years to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful economic life of the asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition are less than their carrying amount. Impairment, if any, is

measured as the amount by which the carrying amount of the long-lived assets exceeds their fair value. The Company did not record any impairment of long-lived assets during the years ended December 31, 2023, 2022 and 2021.

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 and is primarily comprised of product revenue net of returns, administration fees and sales rebates. 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. Administration fees and sales rebates are accounted for as a reduction in revenue, calculated based on the terms agreed to with the customer.

As of December 31, 2023 and 2022, the Company recorded $227,000 and $148,000, respectively, of unbilled receivables, which are included in accounts receivable, net on the 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 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 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 logistics-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.

Research and Development

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of engineering, product development, clinical studies to develop and support the Company's products, regulatory expenses, medical affairs and other costs associated with products and technologies that are in development. Research and development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, clinical studies include costs associated with clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of products used for clinical trials and internal and external costs associated with the Company's regulatory compliance and quality assurance functions, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings, and overhead costs.

Clinical Trials

The Company accrues and expenses costs for its clinical trial activities performed by third parties, including any clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these accruals through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs include design and production costs, including website development, physician and patient testimonial videos, written media campaigns, and other items. Advertising costs of $461,000, $347,000 and $221,000 were expensed during the years ended December 31, 2023, 2022 and 2021, respectively.

Foreign Currency

The Company records net gains and losses resulting from foreign exchange transactions as a component of foreign currency exchange gains or losses in other income (expense), net. The Company had no material foreign currency exchange gains or losses during the years ended December 31, 2023, 2022 and 2021.

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 on the first day of the offering period using an option pricing model for each purchase period. These costs are recognized on a straight-line basis over the offering period.

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 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 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 years ended December 31, 2023, 2022 and 2021, 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 statements of operations and comprehensive loss. Accumulated other comprehensive income (loss) is presented in the accompanying 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):

	Year Ended December 31,		
	2023	2022	2021
Net loss	$ (55,743)	$ (55,010)	$ (49,811)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	38,804,343	35,775,672	34,635,358
Net loss per share, basic and diluted	$ (1.44)	$ (1.54)	$ (1.44)

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:

	December 31,		
	2023	2022	2021
Common stock options	3,632,684	3,839,858	3,780,939
Restricted stock units and performance stock units	3,536,197	1,329,824	530,274
Total	7,168,881	5,169,682	4,311,213

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 years ended December 31, 2023, 2022 and 2021, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

Recently Issued Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segments expenses. ASU 2023-07 became effective for the Company on January 1, 2024. The Company does not believe that the adoption of this new guidance will have a material impact on its segment reporting disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, or ASU 2023-09, which enhances income tax disclosure requirements by requiring specified categories and greater disaggregation within the rate reconciliation table, disclosure of income taxes paid by jurisdiction, and providing clarification on uncertain tax positions and related financial statement impacts. ASU 2023-09 is effective for the Company on January 1, 2025 with early adoption permitted. The Company is currently evaluating the impact of adoption of this new guidance on its income tax 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 December 31, 2023 and 2022 using the inputs defined above (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 19,483	$ —	$ —	$ 19,483
U.S. treasury bills	11,899	—	—	11,899
Commercial paper	—	33,150	—	33,150
Corporate bonds/notes	—	39,438	—	39,438
U.S. government securities	—	17,556	—	17,556
Agency bonds/notes	—	68,677	—	68,677
Total	$ 31,382	$ 158,821	$ —	$ 190,203

	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
Total	$ 74,934	$ 138,540	$ —	$ 213,474

There were no transfers between fair value hierarchy levels during the years ended December 31, 2023, 2022, and 2021.

5. Balance Sheet Components

Investments

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

	December 31, 2023			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 19,483	$ —	$ —	$ 19,483
U.S. treasury bills	11,896	3	—	11,899
Commercial paper	33,160	5	(15)	33,150
Corporate bonds/notes	39,398	55	(15)	39,438
U.S. government securities	17,501	55	—	17,556
Agency bonds/notes	68,693	27	(43)	68,677
Total	$ 190,131	$ 145	$ (73)	$ 190,203
Classified as:				
Cash equivalents				$ 19,483
Short-term investments				161,264
Long-term investments				9,456
Total				$ 190,203

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized 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
Total	$ 213,641	$ 14	$ (181)	$ 213,474
Classified as:				
Cash equivalents				$ 55,158
Short-term investments				158,316
Total				$ 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 December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Amounts maturing within one year	$ 180,747	$ 213,474
Amounts maturing after one year through two years	9,456	—
Total	$ 190,203	$ 213,474

Available-for-sale investments held as of December 31, 2023 had a weighted average days to maturity of 163 days.

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

	December 31, 2023		December 31, 2022	
	Less than 12 months		Less than 12 months	
Assets:	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds/notes	$ 21,842	$ (15)	$ 1,490	$ (13)
Commercial paper	19,684	(15)	—	—
U.S. government securities	—	—	73,329	(164)
Asset-backed securities	—	—	1,994	(4)
Agency bonds/notes	48,964	(43)	—	—
Total	$ 90,490	$ (73)	$ 76,813	$ (181)

There were no available-for-sale investments in an unrealized loss position greater than twelve months as of December 31, 2023 and 2022.

Inventories

Components of inventories were as follows (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 6,512	$ 4,913
Finished products	23,364	14,380
Total inventories	$ 29,876	$ 19,293

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

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2023	2022
Furniture and fixtures	$ 2,052	$ 1,822
Equipment	5,776	5,046
Software	296	296
Leasehold improvements	7,561	7,246
	15,685	14,410
Less: Accumulated depreciation	(7,907)	(5,355)
Add: Construction-in-progress	336	317
Total property and equipment, net	$ 8,114	$ 9,372

Depreciation and amortization expense was $2,696,000, $2,127,000 and $1,032,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued payroll and related expenses	$ 17,113	$ 15,216
Operating lease liability	1,703	1,844
Accrued travel expenses	944	775
Accrued interest payable	517	519
Provision for sales returns	500	540
Accrued royalty expense	405	973
Accrued administration fees and sales rebates	405	338
Accrued professional services	326	781
Accrued clinical expenses	256	249
Deferred revenue	143	253
Accrued other expenses	2,295	477
Total accrued liabilities	$ 24,607	$ 21,965

6. Long-term Debt

Stifel Bank

In October 2020, the Company entered into a Loan and Security Agreement with Stifel Bank which provided for a $50,000,000 loan facility, comprised of a $50,000,000 secured revolving credit facility, with a $2,000,000 subfacility for the issuance of letters of credit and other ancillary banking services, and a $50,000,000 secured term loan facility, provided that amounts outstanding under both facilities may not exceed an aggregate principal amount of $50,000,000 at any time. Interest under the revolving credit facility was the greater of a) 0.5% above the "Prime Rate" as published by *The Wall Street Journal* or b) 4.75%. Interest under the term loan facility was the greater of a) 0.75% above the "Prime Rate" as published by *The Wall Street Journal* or b) 4.75%. The Company drew down $49,000,000 under the term loan facility in October 2020. Concurrent with the Loan and Security Agreement, the Company entered in a Success Fee Agreement in October 2020 with Stifel Bank, which requires that the Company pay Stifel Bank the lesser of 0.75% of the original principal amount of all credit extensions made under the Loan and Security Agreement or $375,000 in the event the Company completes a Liquidity Event (liquidation, merger, sale of the Company or change in control).

On May 27, 2022, in connection with the consummation of the Loan and Security Agreement with Oxford Finance, as noted below, the Company repaid all amounts outstanding under the term loan with Stifel Bank. The Success Fee Agreement obligation of $367,500 survives the Stifel Bank debt repayment and terminates on October 29, 2025. The Company has determined the probability of a Liquidity Event to be remote and accordingly, has not recognized a liability as of December 31, 2023 and 2022.

Oxford Finance

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 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.

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.

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 December 31, 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 December 31, 2023, the Company was in compliance with all applicable financial covenants.

Future payments under the Oxford Finance term loan agreement as of December 31, 2023 are as follows (in thousands):

Year Ending December 31:	Amount
2024	$ 5,719
2025	5,703
2026	45,699
2027	34,517
	91,638
Add: Accretion of closing fees	1,329
	92,967
Less: Amount representing interest	(16,638)
Less: Amount representing debt discount and debt issuance costs	(703)
Present value of minimum payments	$ 75,626

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.

The Company’s non-cancelable operating lease obligation at its facility 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.

Balance sheet information as of December 31, 2023 and 2022 consists of the following (in thousands):

	December 31,	
Operating Lease:	2023	2022
Operating lease right-of-use asset in other non-current assets	$ 6,489	$ 5,081
Operating lease liability in accrued liabilities	$ 1,703	$ 1,844
Operating lease liability in other liabilities	7,304	5,998
Total operating lease liabilities	$ 9,007	$ 7,842

The following table summarizes the Company's operating lease payments as of December 31, 2023 (in thousands):

Year Ending December 31:	Amount
2024	$ 1,991
2025	2,130
2026	2,255
2027	2,068
2028	1,233
Thereafter	1,158
Total lease payments	10,835
Less: imputed interest	(1,828)
Present value of lease liabilities	$ 9,007

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. As of December 31, 2023, the Company had non-cancellable purchase obligations to suppliers of $15,660,000. 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 December 31, 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 December 31, 2023 and 2022.

8. Stockholders' Equity

Preferred Stock

As of December 31, 2023, the Company's restated certificate of incorporation authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

As of December 31, 2023, the Company's restated certificate of incorporation authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 39,165,481 shares were issued and outstanding. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of December 31, 2023, no dividends have been declared to date. Each share of common stock is entitled to one vote.

As of December 31, 2023 and 2022, the Company had reserved common stock for future issuances as follows:

	December 31,	
	2023	2022
Outstanding stock options and equity awards	7,168,881	5,169,682
Reserved for grants of future stock options and equity awards	532,627	2,209,072
Reserved for Performance Stock Units for overperformance	809,225	207,468
Reserved for employee stock purchase plan	1,356,463	1,172,686
Total common stock reserved for future issuance	9,867,196	8,758,908

9. Stock-Based Compensation Plans

In March 2019, the Company's Board of Directors [and stockholders] approved the 2019 Equity Incentive Plan, or 2019 Plan, effective immediately prior to the Company's IPO. The 2019 Plan replaced the prior 2007 Stock Option Plan, or 2007 Plan, and the NeuroCo 2015 Equity Incentive Plan, which the Company assumed in connection with its acquisition of NeuroCo in December 2018, with respect to future grants. The 2019 Plan provides for the grant of ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were initially reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan also include shares reserved but not issued under the prior 2007 Plan, plus any share awards granted under the 2007 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan also include an annual increase on the first day of each fiscal year, equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. As of December 31, 2023, the Company has reserved 7,952,134 shares of common stock for issuance under the 2019 Plan.

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

	Number of Shares
Balances, December 31, 2020	1,790,687
Authorized	1,369,985
Granted/Awarded	(847,080)
Cancelled	163,620
Balances, December 31, 2021	2,477,212
Authorized	1,399,235
Allowance for Performance Stock Units for overperformance	(207,468)
Granted/Awarded	(1,600,996)
Cancelled	141,089
Balances, December 31, 2022	2,209,072
Authorized	1,534,238
Allowance for Performance Stock Units for overperformance	(601,757)
Granted/Awarded	(2,893,796)
Cancelled	284,870
Balances, December 31, 2023	532,627

The exercise price of Incentive Stock Options and Non-Statutory Stock Options 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 options 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 (in Years)	Aggregate Intrinsic Value (in thousands)
Balances, December 31, 2020	4,237,828	$ 16.56	7.38	$ 197,407
Options granted	323,057	53.94		
Options exercised	(643,507)	7.49		
Options cancelled	(136,439)	40.30		
Balances, December 31, 2021	3,780,939	$ 20.45	6.71	$ 91,900
Options granted	587,015	37.69		
Options exercised	(453,199)	7.42		

Options cancelled	(74,897)		41.16		
Balances, December 31, 2022	3,839,858	$	24.22	6.41	$ 112,755
Options granted	19,898		33.57		
Options exercised	(199,642)		7.44		
Options cancelled	(27,430)		47.09		
Balances, December 31, 2023	3,632,684	$	25.02	5.52	$ 7,942
Vested and exercisable at December 31, 2023	3,184,646	$	22.62	5.19	$ 7,942
Vested and expected to vest at December 31, 2023	3,632,684	$	25.02	5.52	$ 7,942

The aggregate intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was $7,857,000, $17,575,000 and $29,355,000, respectively. 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. The weighted-average grant date fair value of options granted during the years ended December 31, 2023, 2022 and 2021 was $17.67, $37.69 and $23.83 per share, respectively. The total fair value of options vested during the years ended December 31, 2023, 2022 and 2021 was $9,207,000, $9,816,000 and $9,076,000, respectively, based on the grant date fair value.

Restricted Stock Units

In March 2020, the Company began awarding restricted stock units, or RSUs, under the 2019 Plan. RSUs generally vest and are settled in shares of common stock over four years in annual equal increments. The total award date fair value of awards provided during the years ended December 31, 2023, 2022 and 2021 was $46,939,000, $30,486,000 and $28,110,000, respectively. The total fair value of awards vested during the years ended December 31, 2023, 2022 and 2021 was $13,203,000, $6,135,000 and $1,893,000, respectively. The fair value of RSUs is based on the closing price of the Company's common stock on the date of award.

A summary of RSU activity for the years ended December 31, 2023, 2022 and 2021 is as follows:

	Number of Restricted Stock Units		Weighted Average Grant Date Fair Value
Balances, December 31, 2020	68,396	$	46.16
Awards granted	524,023		53.64
Awards vested	(34,964)		49.95
Awards cancelled	(27,181)		51.99
Balances, December 31, 2021	530,274	$	53.01
Awards granted	806,513		37.80
Awards vested	(148,239)		52.14
Awards cancelled	(66,192)		44.38
Balances, December 31, 2022	1,122,356	$	42.70
Awards granted	2,162,465		21.71
Awards vested	(410,085)		43.44
Awards cancelled	(147,764)		41.23
Balances, December 31, 2023	2,726,972	$	26.02
Expected to vest at December 31, 2023	2,726,972	$	26.02

Performance Stock Units

In November 2022, the Company began awarding performance stock units, or PSUs, under the 2019 Plan to certain executive officers and key employees. PSUs generally vest at the end of a three year service period, subject to continued service to the Company. The total number of shares of common stock to be issued upon vesting and settlement of the PSUs will be determined based on the total stockholder return, or TSR, of the Company's common stock price relative to a group of Benchmark Companies over a three year performance period and range from 0% to 200% of the target value of shares awarded, depending on the Company's performance against the targeted Benchmark Companies. The total award date fair value of awards provided during the years ended December 31, 2023 and 2022 was $14,950,000 and $16,000,000, respectively.

There was no PSU activity for the year ended December 31, 2021. A summary of PSU activity for the years ended December 31, 2023 and 2022 is as follows:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Balances, December 31, 2021	—	$ —
Awards granted	207,468	77.12
Awards vested	—	—
Awards cancelled	—	—
Balances, December 31, 2022	207,468	$ 77.12
Awards granted	711,433	21.01
Awards vested	—	—
Awards cancelled	(109,676)	76.66
Balances, December 31, 2023	809,225	$ 27.86
Expected to vest at December 31, 2023	809,225	$ 27.86

The shares expected to vest as of December 31, 2023 reflects PSUs awards performance and vesting at 100% of the target value of shares granted.

2019 Employee Stock Purchase Plan

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

As of December 31, 2023, 465,952 shares of common stock have been issued to employees participating in the ESPP and 1,356,463 shares were available for future issuance under the ESPP.

Stock-Based Compensation

The Company estimated the fair value of stock options using the Black–Scholes option pricing model. The fair value of stock options is being amortized on a straight–line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following assumptions for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
	2023	**2022**	**2021**
Expected term (in years)	5.25	5.25 - 6.25	5.25 - 6.25
Expected volatility	55.1%	48.2% - 51.4%	45.0% - 50.4%
Risk-free interest rate	3.94%	1.60% - 3.84%	0.41% - 1.08%
Dividend yield	—%	—%	—%

The fair value of the underlying common stock is based on the closing price of the Company's common stock on The Nasdaq Global Select Market on the date of grant. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company does not have sufficient historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term of options and has opted to use the “simplified method,” whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected stock price volatility assumption was determined by supplementing its historical stock trading volatility with the historical volatilities for industry peers, as the Company does not have sufficient trading history for the Company’s common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company’s common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company’s stock options. The expected dividend assumption is based on the Company’s history and expectation of dividend payouts. The Company has elected to recognize forfeitures of share-based payment awards as they occur.
In November 2022, the Company awarded an aggregate of 207,468 PSUs to certain executive officers that vest at the end of a three year service period based on the TSR of the Company’s common stock price relative to a group of Benchmark Companies measured over three performance periods. The Company estimated the fair value of the PSUs

using the Monte Carlo simulation model, which is being amortized over the requisite service period of the awards. The fair value of the PSUs was estimated using the following assumptions for the year ended December 31, 2022: peer companies volatility of 59.4%, Company volatility of 60.6%, risk-free interest rate of 4.09%-4.20%, correlation with index of 0.41, and dividend yield of 0%.

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 for the year ended December 31, 2023: 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%.

In November 2023, the Company awarded an aggregate of 612,083 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 for the year ended December 31, 2023: peer companies volatility of 56.9%, Company volatility of 71.1%, risk-free interest rate of 4.72%, correlation with index of 0.35, and dividend yield of 0%.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following assumptions for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
	2023	**2022**	**2021**
Expected term (in years)	0.50	0.50	0.50
Expected volatility	47.4% - 119.5%	51.6% - 74.5%	46.9% - 51.6%
Risk-free interest rate	4.64% - 5.43%	0.07% - 4.64%	0.03% - 0.10%
Dividend yield	—%	—%	—%

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

	Year Ended December 31,		
	2023	**2022**	**2021**
Cost of goods sold	$ 1,671	$ 1,138	$ 635
Research and development expenses	7,589	5,240	2,909
Selling, general and administrative expenses	29,633	18,645	11,068
Total stock-based compensation expense	$ 38,893	$ 25,023	$ 14,612

As of December 31, 2023, there was total unrecognized compensation costs of $5,645,000 related to stock options expected to be recognized over a period of approximately 1.63 years, a total of $73,195,000 of unrecognized compensation costs related to unvested RSUs and PSUs expected to be recognized over a period of approximately 2.76 years and $679,000 of unrecognized compensation costs related to the ESPP, which the Company will recognize over 0.38 years.

10. Income Taxes

The components of income before taxes are as follows (in thousands):

	Year Ended December 31,		
	2023	**2022**	**2021**
United States	$ (55,743)	$ (55,010)	$ (49,811)
International	—	—	—
Net loss before income taxes	$ (55,743)	$ (55,010)	$ (49,811)

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Tax at federal statutory rate	$ (11,706)	$ (11,552)	$ (10,460)
State taxes, net of federal benefit	(2,311)	(2,206)	(1,852)
Permanent differences	(392)	(2,893)	(5,224)
Change in valuation allowance	11,549	18,237	17,918
Limitation of compensation deduction under IRS Sec.162(m)	4,320	10	—
General business credits	(1,536)	(1,166)	(852)
Other	119	(401)	490
Provision for income taxes	$ 43	$ 29	$ 20

The Company's provision for income taxes amounts are not significant and are included within other income (expense) on the statements of operations and comprehensive loss.

Significant components of the Company's net deferred tax assets as of December 31, 2023 and 2022 consist of the following (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 85,945	$ 82,768
Research and development credits	10,753	8,898
Capitalized start-up costs/Intangibles	—	1
Section 174 R&D capitalization	12,892	7,816
Accruals and reserves	2,775	2,820
Stock-based compensation	10,353	8,209
Operating lease liability	2,272	1,973
Interest limitation	1,114	2,013
Total deferred tax assets	126,104	114,498
Less: Valuation allowance	(122,993)	(111,444)
Deferred tax liabilities:		
Operating lease asset	(1,636)	(1,278)
Property and equipment	(1,475)	(1,776)
Total deferred tax liabilities	(3,111)	(3,054)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management believes it is more likely than not that the deferred tax assets will not be realized; accordingly, a valuation allowance has been established on U.S. net deferred tax assets. The valuation allowance increased $11,549,000, $18,237,000 and $17,918,000 during the years ended December 31, 2023, 2022 and 2021, respectively.

As of December 31, 2023, the Company had net operating loss carryforwards of approximately $331,957,000 and $288,608,000 for federal and state income tax purposes, respectively. The federal and state net operating loss carryforwards begin to expire in 2027 and 2024, respectively. Federal NOL carryforwards generated in tax years beginning in 2018 are not subject to expiration. Federal NOLs that arose on or after January 1, 2018 can be carried forward indefinitely against future income, but can only be used to offset a maximum of 80% of the Company's federal taxable income in any year.

The federal and state net operating loss carryforwards may be subject to significant limitations under Section 382 and Section 383 of the Internal Revenue Code and similar provisions under state law. Federal tax legislation enacted in December 2017, commonly known as the Tax Cuts and Jobs Act, contains provisions that limit the federal net operating loss carryforwards that may be used in any given year in the event of special occurrences, including significant ownership changes. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders, who own at least 5% of the Company's stock, increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Company may have previously experienced, and may in the future experience, one or more Section 382 "ownership changes," including in connection with the Company's initial public

offering. If so, the Company may lose some or all of the tax benefits of its NOLs and tax credits. The extent of such limitations for prior years, if any, has not yet been formally determined.

Under the Tax Cuts and Jobs Act, research and development expenditures are no longer fully deductible and are required to be capitalized and amortized under Section 174 of the Internal Revenue Code in tax years beginning on or after January 1, 2022. The capitalized research expenses must be amortized over five years for research performed in the U.S. and 15 years for research performed outside the U.S. The mandatory capitalization requirement increased the Company's deferred tax assets, which were fully offset by a valuation allowance.

At December 31, 2023, the Company had $10,122,000 and $5,869,000 of federal and state research and development credit carryforwards, respectively, on a tax return basis. If not utilized, the federal credits will expire beginning in 2027. The California research and development credits can be carried forward indefinitely.

As of December 31, 2023, the Company had $4,364,000 of unrecognized tax benefits. The Company does not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized tax benefits would increase or decrease within twelve months of the year ended December 31, 2023. If recognized, $0 would affect the effective tax rate.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. There was no such expense recorded during the years ended December 31, 2023, 2022 and 2021.

A reconciliation of the unrecognized tax benefits from January 1, 2021 to December 31, 2023 is as follows (in thousands)

	December 31,		
	2023	2022	2021
Balance at the beginning of year	$ 3,788	$ 3,314	$ 2,019
Increases related to current years' tax positions	571	474	704
Increases related to prior years' tax positions	5	—	591
Balance at end of year	$ 4,364	$ 3,788	$ 3,314

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal and state tax examination.

11. 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. Beginning in January 2020, the Company started matching employees' contributions to the 401(k) plan at 50% of the first 5% of compensation deferred to the 401(k) plan and at 50% of the first 6% of compensation deferred effective January 1, 2022. The Company's matching contributions were $2,256,000, $1,872,000 and $1,313,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the framework in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on that evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

The effectiveness of the Company’s internal control over financial reporting as of December 31, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Part II, Item 8 under the caption “Report of Independent Registered Public Accounting Firm” of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting can also be circumvented by collusion or improper management override of the controls. Projections of any evaluation of controls effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information

Rule 10b5-1 Plan and Non-Rule 10b5-1 Trading Arrangement Adoptions, Terminations, and Modifications

During the three months ended December 31, 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required in response to this item is incorporated herein by reference to the information contained under the captions entitled “Proposal No. 1 Election of Directors—Information about Director Nominees,” “Executive Officers,” and “Corporate Governance” in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

During the fourth quarter of 2023, we did not make any material changes to the procedures by which stockholders may recommend nominees to our board of directors, as described in our definitive proxy statement for our 2023 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required in response to this item is incorporated herein by reference to the information contained under the captions entitled “Executive Compensation,” “Compensation Discussion and Analysis,” “Compensation Committee Report” and “Director Compensation” in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required in response to this item is incorporated herein by reference to the information contained under the caption entitled “Stock Ownership” in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required in response to this item is incorporated herein by reference to the information contained under the captions entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance—Director Independence” in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services

The information required in response to this item is incorporated herein by reference to the information contained under the captions entitled “Proposal No. 3: Ratification of Appointment of Independent Registered Public Accounting Firm—Audit, Audit-Related, Tax, and Other Fees” and “Proposal No. 3: Ratification of Appointment of Independent Registered Public Accounting Firm—Pre-Approval Policies and Procedures” in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibits and Financial Statement Schedule

(a) Financial Statements.

The financial statements included in "Index to Financial Statements" in Part II, Item 8 are filed as part of this Annual Report on Form 10-K.

(b) Financial Statement Schedule.

All other schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto. The table below presents Schedule II, Valuation and Qualifying Accounts, detailing the activity of the allowance for credit losses for the years ended December 31, 2023, 2022 and 2021 (in thousands):

Description	Balance at Beginning of Year	Charged to Expenses	Write Offs	Balance at End of Year
Allowance for credit losses:				
Year ended December 31, 2023	$ 3	$ 45	$ 22	$ 26
Year ended December 31, 2022	$ 6	$ (3)	$ —	$ 3
Year ended December 31, 2021	$ 13	$ 6	$ 13	$ 6

(c) Exhibits.

The following exhibits are incorporated herein by reference or are filed or furnished with this Annual Report on Form 10-K as indicated below:

Exhibit Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation of Silk Road Medical, Inc.					*
3.2	Amended and Restated Bylaws of Silk Road Medical, Inc. effective as of March 15, 2023	8-K	001-38847	3.1	3/15/2023	
4.1	Specimen Common Stock Certificate of Silk Road Medical, Inc.	S-1	333-233044	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	333-233044	4.3	8/6/2019	
4.3	Description of Silk Road Medical, Inc. securities registered pursuant to Section 12 of the Securities Exchange Act of 1934					*
10.1+	Form of Indemnification Agreement between Silk Road Medical, Inc. and each non-employee director and executive officer					*
10.2+	Silk Road Medical, Inc. 2007 Stock Plan, as amended, and related form agreements	S-1	333-233044	10.2	8/6/2019	
10.3+	Silk Road Medical, Inc. 2019 Employee Stock Purchase Plan	S-1	333-233044	10.3	8/6/2019	
10.4+	Silk Road Medical, Inc. Executive Incentive Compensation Plan	S-1	333-233044	10.4	8/6/2019	
10.5+	Silk Road Medical, Inc. 2019 Equity Incentive Plan					*
10.6+	Form of Silk Road Medical, Inc. 2019 Equity Incentive Plan Stock Option Agreement					*
10.7+	Form of Silk Road Medical, Inc. 2019 Equity Incentive Plan Restricted Stock Unit Agreement	8-K	001-38847	10.5	11/2/2023	
10.8+	Form of Silk Road Medical, Inc. 2019 Equity Incentive Plan Performance Stock Unit Agreement	10-Q	001-38847	10.1	5/9/2023	
10.9+	Form of Employment Agreement between Silk Road Medical, Inc. and each executive officer					*
10.10+	Employment Offer Letter Agreement dated October 30, 2023 between Silk Road Medical, Inc. and Charles McKhann	8-K	001-38847	10.1	11/2/2023	
10.11+	Executive Retirement and Transition Agreement effective as of November 2, 2023 between Silk Road Medical, Inc. and Erica J. Rogers	8-K	001-38847	10.7	11/2/2023	
10.12+	Consulting Agreement effective as of November 2, 2023 between Silk Road Medical, Inc. and Erica J. Rogers	8-K	001-38847	10.8	11/2/2023	
10.13+	Confirmatory Employment Letter effective as of March 21, 2019 between Silk Road Medical, Inc. and Erica Rogers	S-1	333-233044	10.13	8/6/2019	
10.14+	Confirmatory Employment Letter effective as of March 21, 2019 between Silk Road Medical, Inc. and Lucas Buchanan	S-1	333-233044	10.14	8/6/2019	

Exhibit Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.15+	Confirmatory Employment Letter effective as of March 21, 2019 between Silk Road Medical, Inc. and Andrew Davis	S-1	333-233044	10.16	8/6/2019	
10.16+	Confirmatory Employment Letter dated June 29, 2022 between Silk Road Medical, Inc. and Kevin Klemz	10-K	001-38847	10.17	2/28/2023	
10.17+	Confirmatory Employment Letter effective as of March 21, 2019 between Silk Road Medical, Inc. and Richard Ruedy	S-1	333-233044	10.15	8/6/2019	
10.18+	Letter Agreement dated September 15, 2023 between Silk Road Medical, Inc. and Andrew Davis	8-K	001-38847	10.1	9/15/2023	
10.19+	Change in Control and Severance Agreement effective as of November 2, 2023 between Silk Road Medical, Inc. and Charles McKhann	8-K	001-38847	10.3	11/2/2023	
10.20+	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Erica Rogers	10-Q	001-38847	10.4	8/8/2023	
10.21+	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Lucas Buchanan	10-Q	001-38847	10.5	8/8/2023	
10.22+	Amended and Restated Change in Control and Severance Agreement effective as of June 22, 2022 between Silk Road Medical, Inc. and Andrew Davis	10-Q	001-38847	10.6	8/8/2023	
10.23+	Change in Control and Severance Agreement effective as of August 15, 2022 between Silk Road Medical, Inc. and Kevin Klemz	10-K	001-38847	10.22	2/28/2023	
10.24+	Change in Control and Severance Agreement effective as of March 21, 2019 between Silk Road Medical, Inc. and Richard Ruedy	S-1	333-233044	10.19	8/6/2019	
10.25#	Supply Agreement effective as of October 21, 2011 between Silk Road Medical, Inc. and Cordis Corporation, as amended by the Amendment dated March 12, 2012, the Second Amendment to the Supply Agreement dated July 12, 2012, the Third Amendment to the Supply Agreement dated April 19, 2013 and the Fourth Amendment to the Supply Agreement dated April 9, 2018	S-1	333-233044	10.6	8/6/2019	
10.26†	Fifth Amendment to Supply Agreement entered into 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	
10.27#	License Agreement effective as of December 17, 2010 between Silk Road Medical, Inc. and Cordis Corporation	S-1	333-233044	10.7	8/6/2019	
10.28†	First Amendment to License Agreement entered into 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	
10.29	Quality Assurance Agreement effective as of May 4, 2015 among Silk Road Medical, Inc. and Lake Region Medical and affiliates	S-1	333-233044	10.8	8/6/2019	
10.30#	Amended and Restated Manufacturing and Supply Agreement entered into as of January 10, 2018 between Silk Road Medical, Inc. and Galt Medical Corporation	S-1	333-233044	10.9	8/6/2019	
10.31†	IP License Agreement dated and effective as of May 12, 2016 between Silk Road Medical, Inc. and Route 92 Medical, Inc.	10-Q	001-38847	10.14	5/10/2022	
10.32†	IP Assignment and License Agreement dated and effective as of May 12, 2016 between Silk Road Medical, Inc. and Route 92 Medical, Inc.	10-Q	001-38847	10.15	5/10/2022	
10.33†	Loan and Security Agreement dated as of May 27, 2022 between Silk Road Medical, Inc. and Oxford Finance, LLC	8-K	001-38847	10.1	5/31/2022	
10.34	First Amendment to Loan and Security Agreement entered into as of June 13, 2022 and effective as of May 27, 2022 between Silk Road Medical, Inc. and Oxford Finance, LLC	10-Q	001-38847	10.17	8/9/2022	
10.35	Lease Agreement dated as of November 30, 2017 between Hanover Properties Ltd. and Silk Road Medical, Inc.	S-1	333-233044	10.11	8/6/2019	
10.36	First Amendment to Lease dated as of August 27, 2018 between Hanover Properties Ltd. and Silk Road Medical, Inc.					*
10.37	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	
10.38	Lease Agreement effective as of May 12, 2021 between ARHC UHPTHMN01 LLC and Silk Road Medical, Inc.	10-Q	001-38847	10.23	8/6/2021	
10.39	First Amendment to Lease Agreement entered into as of June 30, 2022 between Silk Road Medical, Inc. and Parkers Lake Medtech LLC	10-Q	001-38847	10.18	8/9/2022	
10.40	Second Amendment to Lease Agreement entered into as of September 15, 2022 between Silk Road Medical, Inc. and Parkers Lake Medtech LLC	10-Q	001-38847	10.1	11/9/2022	
23.1	Consent of Independent Registered Public Accounting Firm					*
24.1	Power of Attorney, reference is made to the Signatures page to this Form 10-K					*
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					*

Exhibit Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	Filed/Furnished Herewith
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					**
97.1	Silk Road Medical, Inc. Clawback Policy					*
101.INS	XBRL Instance 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.

** Furnished herewith. 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan or arrangement.

† Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K.

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant of confidential treatment. The omitted information has been filed separately with the SEC.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

SILK ROAD MEDICAL, INC.

February 28, 2024 By: /s/ Charles S. McKhann
Charles S. McKhann
Chief Executive Officer

February 28, 2024 By: /s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Operating Officer and Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Charles S. McKhann, Lucas W. Buchanan and Kevin M. Klemz, and each of them acting individually, as such person's true and lawful attorneys-in-fact and agents, with full power of each to act alone, with full powers of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Charles S. McKhann Charles S. McKhann	Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2024
/s/ Lucas W. Buchanan Lucas W. Buchanan	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)	February 28, 2024
/s/ Mhairi L. Jones Mhairi L. Jones	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	February 28, 2024
/s/ Rick D. Anderson Rick D. Anderson	Director	February 28, 2024
/s/ Kevin J. Ballinger Kevin J. Ballinger	Director	February 28, 2024
/s/ Tanisha V. Carino Tanisha V. Carino	Director	February 28, 2024
/s/ Tony M. Chou Tony M. Chou, M.D.	Director	February 28, 2024
/s/ Jack W. Lasersohn Jack W. Lasersohn	Chair of the Board of Directors	February 28, 2024
/s/ Elizabeth H. Weatherman Elizabeth H. Weatherman	Director	February 28, 2024
/s/ Donald J. Zurbay Donald J. Zurbay	Director	February 28, 2024

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