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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, 2021
OR

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

For transition period from to
Commission File Number 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SILK	Nasdaq Global Select Market

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, 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. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant 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. ☒

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 $1.6 billion as of June 30, 2021 based on the closing sale price of the registrant's common stock on the NASDAQ Global Select Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2022, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 35,010,136.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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CAUTIONARY NOTES 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 and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

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

- our plans to conduct further clinical trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or to obtain regulatory approvals or clearances or otherwise;
- the expected use of our products by physicians;
- our expectations regarding the number of procedures that will be performed with our products, the number of physicians we expect to train, and the number of our sales territories;
- our ability to obtain, maintain and expand regulatory clearances for our current products and any new products we create;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued expansion of our sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products and our business;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our ability to identify and develop new and planned products and/or acquire new products;
- our expectations regarding the impact of the COVID-19 pandemic on our business;
- developments and projections relating to our 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 assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

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. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care.

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 the benefits of innovative 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 are the first and only company to obtain FDA approvals, secure specific Medicare reimbursement coverage, and commercialize products engineered and indicated specifically for transcarotid use, in patients who require carotid revascularization and are at high risk for adverse events from carotid endarterectomy and who meet certain treatment criteria. As of December 31, 2021, more than 40,000 TCAR procedures have been performed globally, including more than 13,900 in the United States in 2021.

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 4.3 million people with carotid artery disease in the United States in 2020, with an estimated 433,000 new diagnoses in 2021, 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. We believe this represents an unacceptable trade-off relative to the current standard of care of CEA. As such, after almost 30 years of development, CAS has achieved limited adoption and narrow reimbursement coverage in the United States. CEA remains the standard of care and represented approximately 82% of the approximately 169,000 carotid revascularization procedures performed in the United States in 2021. 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 that addresses 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 433,000 new carotid artery disease diagnoses that occurred in the United States in 2021, we believe a total annual U.S. market opportunity of approximately $3.1 billion exists for our portfolio of TCAR products. There were approximately 169,000 carotid revascularization procedures performed in 2021, which we estimate to represent a market conversion opportunity greater than $1.2 billion. More than 13,900 TCAR procedures were performed in 2021 in the United States using our products, representing just over 3% 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 peer-reviewed journals representing outcomes in more than 7,000 patients to date. 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 thirty-day stroke rate of 0.6% in the FDA-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, or TSP, 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 1.6% for TCAR versus 3.1% for CAS. The differences 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 postoperative myocardial infarction and cranial nerve injury after TCAR compared to CEA, with no differences in the rates of in-hospital stroke/death (1.6% TCAR and 1.6% CEA).

We manufacture the ENROUTE NPS at our facility in Sunnyvale, California and distribute our portfolio of TCAR products from our facilities in Sunnyvale, California and Plymouth, Minnesota. We market and sell our products in the United States through a direct sales organization consisting of 64 sales representatives, known as area managers, or AMs, and 62 clinical support specialists, known as therapy development specialists, or TDSs, as of December 31, 2021, that are focused on driving adoption of TCAR among the approximately 2,750 physicians and 750 hospitals in the United States that we believe are responsible for approximately 80% of carotid revascularization procedures each year. While our current commercial focus is on the U.S. market, our ENROUTE NPS and ENROUTE stent have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We are also pursuing regulatory clearances in China and Japan.

TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG classifications. In September 2016, the Centers for Medicare and Medicaid Services, or CMS, made coverage available for TCAR in symptomatic and asymptomatic patients at high risk for adverse events from CEA, or high surgical risk, treated at facilities participating in the Society for Vascular Surgery's TCAR Surveillance Project using FDA-cleared and approved transcarotid devices. Our ENROUTE NPS and stent are currently the only FDA-cleared and approved transcarotid devices. Carotid artery disease is most often a disease of the elderly and, as such, CMS is the primary payer for carotid revascularization procedures. We estimate that the high surgical risk patient population represents approximately two-thirds of the treated patient population, with the remaining one-third represented by standard surgical risk patients. We are pursuing expansion of FDA labeling for the ENROUTE stent, currently indicated for use in certain patients at high surgical risk, and upon FDA approval, pursue CMS coverage of TCAR in the standard surgical risk patient population.

We have experienced considerable growth since we began commercializing our products in the United States in late 2015. Our revenue increased to $101.5 million for the year ended December 31, 2021 compared to $75.2 million and $63.4 million for the years ended December 31, 2020 and 2019, respectively, representing growth of 35% and 60%, respectively. Our net losses were $49.8 million, $47.4 million and $52.4 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, 2020 and 2019, our accumulated deficit was $288.7 million, $238.9 million and $191.5 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.

Today, our product portfolio consists of the following four single use components. Based on our experience, the full product portfolio is used in the majority of TCAR procedures. In the future we plan to continue to expand our product portfolio to include additional tools and devices to support the TCAR procedure.

ENROUTE Transcarotid Neuroprotection System		• Used to directly access the common carotid artery and initiate temporary blood flow reversal • Allows for flow modulation enabling lesion imaging and patient tolerability • Only FDA-cleared transcarotid neuroprotection system
ENROUTE Transcarotid Stent System		• Self-expanding, self-tapering stent that conforms to patient • Transcarotid delivery system improves the accuracy and the overall ergonomics of the TCAR procedure • Only FDA approved transcarotid stent system
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		• Main conduit for navigating and crossing the target lesion for delivery of interventional devices • Short working length and proprietary tip designed for TCAR

The ENROUTE NPS (510(k) K153485) is cleared for transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy, and the ENROUTE stent (PMA P140026) is approved for use in conjunction with the ENROUTE NPS for the treatment of patients at high risk for adverse events from CEA who require carotid revascularization and meet certain criteria.

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 peer-reviewed journals representing outcomes in more than 7,000 patients 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. The results of the pivotal phase of the ROADSTER study were published in November 2015 in the Journal of Vascular Surgery. 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 in 692 patients. Data on TCAR outcomes also continues to accrue through the Society for Vascular Surgery-sponsored TCAR Surveillance Project, an ongoing real-world, open-ended registry. The VQI stated that close to 28,000 TCAR procedures have been submitted to the registry as of January 19, 2022.

Summary of Key Clinical Trials

	PROOF	ROADSTER	ROADSTER 2	TCAR Surveillance Project
Study Type	First in Human CE Marking DW-MRI Sub-Study	U.S. Pivotal IDE 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	Open Ended
Profile	High Surgical Risk and Standard Surgical Risk	High Surgical Risk	High Surgical Risk	High Surgical Risk
Status/Publication	Complete J Endovasc Ther. 2017 Apr;24(2):265-270	Complete J Vasc Surg. 2015 Nov;62(5):1227-34 (pivotal cohort only)	Complete Stroke 2020; 51: 2620-2629	Ongoing - 28,000 patients as of January 19, 2022 Complete: Ann Surg. 2020 Sep 15 Complete:JAMA. 2019; 322(23): 2313-2322 Complete: J Am Coll Surg 2020; 230: 113-120
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

Summary of TCAR Clinical Trial Outcomes

	PROOF	Pooled ROADSTER		ROADSTER 2	
	ITT population	ITT population	Per-protocol	ITT 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 ITT 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 CE marking of the ENROUTE NPS. Data from the PROOF Study were also used to support FDA approval of the IDE for the ROADSTER Study.

The PROOF Study enrolled patients that were classified as high surgical risk, as well as patients classified as standard surgical risk. The results from the PROOF Study demonstrated that 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.

Additionally, a sub-study of 56 patients underwent pre- and post-procedure diffusion-weighted magnetic resonance image scanning, or DW-MRI, to detect new white lesions on the ipsilateral side of the brain as a sensitive surrogate marker of microemboli and brain injury. The analysis resulted in only 18% of the treatment population presenting with ipsilateral new white lesions, which was also comparable to that reported for CEA in prior clinical trials and significantly less than that reported in prior CAS trials.

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. Key secondary endpoints included acute device, technical and procedural success at 30 days, as well as cranial nerve injury at six months. The results of the ROADSTER Study were analyzed on an “intention to treat,” or ITT basis, as well as a “per protocol,” or PP basis. The ITT results accounted for all patients enrolled in the clinical trial, including patients treated despite major protocol deviations. The PP results included only patients that met all of the inclusion and none of the exclusion criteria and who were compliant with the protocol-mandated study medication regimen. There were no patients lost to follow-up in either the ITT or PP cohorts.

On an ITT basis, the primary endpoint event rate in the pivotal phase of the ROADSTER Study was a 3.5% hierarchical composite rate of stroke, death or myocardial infarction at 30 days, comprised of two strokes, or a 1.4% incidence, two deaths, or a 1.4% incidence, and one myocardial infarction, or a 0.7% incidence. Both deaths were respiratory in nature and were independently adjudicated as not related to the device. There were no site-reported cardiovascular or neurologic deaths, although our independent clinical events committee adjudicated one death as cardiovascular. There were no major strokes. There was one report of an acute cranial nerve injury, representing a 0.7% incidence, which resolved within six months. These data supported FDA 510(k) clearance of the ENROUTE NPS.

In the PP analysis, the primary endpoint event rate was 2.9%, comprised of one stroke, or a 0.7% incidence, two deaths, or a 1.5% incidence, and one myocardial infarction, or a 0.7% incidence.

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 as the pivotal phase of the ROADSTER Study. The results of the continued access phase were similar to those reported in 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, to support our pre-market approval application for the ENROUTE stent. The ENROUTE and Precise stent systems share the same design for the stent implant itself, and differ only in the design of the delivery system. Based on this data, the PMA for the ENROUTE stent was approved in May 2015.

We also initiated a separate sub-study of patients treated PP 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% and the mortality rate was 3.7% past 30 days.

ROADSTER 2 U.S. Post-Market Approval Study

The ROADSTER 2 Post 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. Like the sub-analysis from the ROADSTER Study that led to PMA approval of the ENROUTE stent, the primary endpoint, which was assessed on a per-protocol (PP) basis, was the rate of procedural success at 30 days in high surgical risk patients with a three year minimum life expectancy.

The ROADSTER 2 post approval study enrolled 692 patients at 42 sites. 61.8% of the participating patients were treated by physicians who did not participate in the ROADSTER Study. The FDA mandated that at least 70% of the sites be new sites. Enrollment commenced in 2015. Enrollment and final 30-day follow-up assessments were completed in 2019 and the results were published in the journal *Stroke* in August 2020.

In the ROADSTER 2 final report submitted to the FDA in October 2019, data on 632 patients treated PP were presented. The procedural success rate in ROADSTER 2 was 97.9%. The lower bound of the 2-sided 95% exact binomial confidence intervals of the observed procedural success rate significantly exceeds the a priori threshold of 85% ($p<0.0001$). The primary endpoint of ROADSTER 2 was met and, as a result, the rate of procedural success in ROADSTER 2 compares favorably to the rate of procedural success in the ROADSTER Sub-Study population, which was 98.1%.

Data from a subset of ROADSTER 2 subjects (n=155) is being analyzed to assess the incidence of ipsilateral stroke from day 31 through day 365 post-procedure. These data are expected to be published in the future.

The Society for Vascular Surgery’s TCAR Surveillance Project

The TCAR Surveillance Project (TSP) 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 carotid artery while reversing blood flow within the carotid artery. It is intended to compare TCAR with CEA in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative, or 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. 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 CAS and CEA procedures are also collected in their respective registries within the Society for Vascular Surgery VQI, comparisons of TCAR to CAS or CEA can also be made.

Eligible patients must meet the inclusion criteria specified for the TCAR Surveillance Project. Generally, patients must be at high surgical risk and 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 stent and the ENROUTE NPS are the only such devices cleared and approved by the FDA. TCAR procedures entered into the Society for Vascular Surgery VQI CAS registry for the TCAR Surveillance Project are eligible for reimbursement by Medicare if the patients meet the requirements set forth above. We believe the TCAR Surveillance Project represents a unique collaboration between a physician specialty society, the FDA and CMS. We believe it also marks the first time that CMS has granted broader reimbursement for a stent-based treatment paradigm for carotid artery disease in a registry not managed by industry.

The TCAR Surveillance Project is intended to be a repository for TCAR procedures and outcomes data to broaden the clinical evidence base for TCAR. TCAR is one of many surgical and endovascular procedures that is tracked by the Society for Vascular Surgery VQI. Over time, it is expected that physicians and academic researchers will 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.

The primary outcome measure of the TCAR Surveillance Project is one-year ipsilateral stroke or death. The TCAR Surveillance Project also tracks in-hospital stroke, death and myocardial infarction. Other secondary outcomes, such as cranial nerve injury and re-intervention, are also being reported. For the secondary outcome measures, any stroke will be counted and in-hospital stroke events are not limited to the ipsilateral side.

The Society for Vascular Surgery Vascular Quality Initiative has reported that 565 centers have contributed almost 28,000 TCAR procedures to the CAS VQI registry as of January 19, 2022.

TCAR Surveillance Project: TCAR vs. CAS

In a study published in the *Journal of the American Medical Association* in December of 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 of 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.

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 and Planned TCAR Studies

DW-MRI Studies

In addition to the Society for Vascular Surgery's TCAR Surveillance Project, we have two studies focused on evaluating the incidence of new white lesions using DW-MRI following the TCAR procedure. In both studies, the evaluation of the presence of new white lesions by DW-MRI is conducted by an independent neuroradiologist.

The EU DW-MRI study completed enrollment of 31 patients at three sites in the European Union in the first quarter of 2021. The objective was to evaluate the incidence of new white lesions, as detected on DW-MRI in recently symptomatic patients. The primary endpoint was the incidence of new white lesions by DW-MRI post-procedure. Study follow-up is complete and data from the study are under analysis.

A similar study was conducted at five hospitals in the United States and two in the European Union. The study completed enrollment of 55 patients in the fourth quarter of 2021. The objective was to also evaluate the incidence of post-procedure new white lesions by DW-MRI compared to baseline in asymptomatic or symptomatic patients who underwent the TCAR procedure. The primary endpoint was the incidence of ipsilateral new white lesions by DW-MRI post-procedure. Study follow-up is complete and data from the study are under analysis.

Our Commercial Strategy

We believe there are approximately 2,750 physicians that perform an estimated 80% of annual carotid revascularization procedures in the United States. Vascular surgeons, who we believe represent the specialty most frequently responsible for managing the care of and receiving referrals for patients with carotid artery disease, 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.

In the United States, we market and sell our portfolio of TCAR products through a direct sales organization consisting of 64 sales representatives, known as area managers, or AMs, as of December 31, 2021. The AMs are complemented by one or more Therapy Development Specialists 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. We do not currently sell our products in markets outside the United States.

Our AMs 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. In addition, they help physicians and

their staff to build TCAR programs, drive certain referral initiatives, and provide resources to help with practice development, reimbursement and patient education. Together with the TDSs, 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.

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.

Professional Education and Sales Training

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 group, socially distanced formats as needs have dictated during the COVID-19 pandemic. We also provide training through physician proctors on an as needed basis. As of December 31, 2021, we have trained and certified over 2,000 physicians in the United States.

Through the Office of Medical Affairs, 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 the entire customer experience in addition to their technical aptitude.

Coverage and Reimbursement

Since achieving regulatory clearances and approvals for our portfolio of TCAR products, we have made significant progress securing reimbursement codes and payer coverage.

During the ROADSTER trial, the Society for Vascular Surgery helped to guide modifications of existing CPT reimbursement coding descriptions to ensure their applicability to TCAR. In 2015, we also confirmed with CMS that TCAR, like CAS, was considered under the purview of the National Coverage Determination 20.7, or NCD, for Percutaneous Transluminal Angioplasty.

According to the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project, CMS is the primary payer for carotid revascularization procedures, representing approximately 79% of the payer mix for CEA and CAS procedures in 2017. TCAR is currently covered by CMS in high surgical risk patients who are symptomatic with greater than or equal to 70% stenosis. As of September 2016, TCAR is also covered by CMS in the TCAR Surveillance Project for high surgical risk patients who are either symptomatic with greater than or equal to 50% stenosis or asymptomatic with greater than or equal to 80% stenosis. We intend to seek FDA label expansion for our ENROUTE stent and CMS coverage for TCAR in standard surgical risk patients, as well as seek new and expanded coverage for TCAR in commercial payer coverage policies.

TCAR, like CAS, is only reimbursed by Medicare as an inpatient procedure and therefore reimbursed to hospitals under the 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 only available in facilities certified to have met CMS's minimum facility standards for performing carotid artery stenting, which include local credentialing requirements. 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 (MCC), 035 when the patient presents with a complication or co-morbidity (CC), or 036 for patients without complications or co-morbidities.

Payment for Physicians

The 2022 national average physician professional fee payment for CPT code 37215 is approximately $1,009. 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 2022 national average physician professional fee payment is $1,147.

Payment for Hospitals

The national unadjusted 2022 payment amounts for MS-DRGs 034, 035 and 036 are $26,233, $15,429 and $12,215, 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 $15,254 in 2022. 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. We expect the national unadjusted 2022 payment amounts for MS-DRGs 037, 038 and 039 to be $21,614, $10,939 and $7,518, respectively. Based on prior procedure volumes, we estimate that the weighted average payment amount across these three Extracranial Procedure MS-DRGs to be $9,920. 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.

Coverage

Pursuant to the NCD 20.7 for Percutaneous Transluminal Angioplasty, TCAR is TCAR is currently covered by CMS in high surgical risk patients who are symptomatic with greater than or equal to 70% stenosis. The TCAR Surveillance Project is an FDA-approved extension study, and as such, as of September 2016, TCAR is also covered by CMS in the VQI's TCAR Surveillance Project for high surgical risk patients who are either symptomatic with greater than or equal to 50% stenosis or asymptomatic with greater than or equal to 80% stenosis. For billing purposes, facilities and providers can submit claims for the TCAR Surveillance Project using National Clinical Trial identifier NCT02850588.

Patients at high risk for adverse events from CEA are defined as having significant comorbidities or anatomic risk factors and would be poor candidates for CEA. Symptoms of carotid artery stenosis include carotid transient ischemic attack, focal cerebral ischemia producing a nondisabling stroke, and transient monocular blindness. The determination that a patient is at high risk for adverse events from CEA and the patient's symptoms arising from carotid artery stenosis must be documented in the patient's medical records.

CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS standards in order to receive coverage for CAS, inclusive of TCAR, for high surgical risk patients. Participation in the Society for Vascular Surgery's Vascular Quality Initiative can provide evidence of compliance to these standards to CMS. The ENROUTE NPS and the ENROUTE stent are also included in the CREST-2 Companion Registry, or C2R, but not in the CREST 2 randomized clinical trial itself. The objective of C2R is to promote the rapid initiation and completion of enrollment in the CREST-2 randomized clinical trial (clinicaltrials.gov ID NCT02089217). Patient eligibility in C2R includes standard surgical risk and high surgical risk patients with symptomatic or asymptomatic carotid artery disease. Patients will be followed for the occurrence of post-procedural complications. The primary safety and quality endpoint for C2R is the occurrence of any stroke or death within the 30-day period following the stenting procedure. The safety and quality results from C2R will guide selection of interventionists for participation in the CREST-2 randomized clinical trial. Enrollment into C2R began in 2015 and will continue until publication of the primary results of the randomized trial. Providers can bill CMS for TCAR patients enrolled in this registry using NCT02240862.

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 and management, data collection and biostatistics 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. We believe our research and development capabilities, clinical and regulatory organizations and unique insights will enable us to continue to lead this emerging category.

Following completion of our ROADSTER 2 Post-Approval Study and our US and European Union DW-MRI studies, our clinical programs are currently focused on applying our technology in the neurovascular space, specifically for the treatment of acute ischemic stroke patients, as well as preparing for a post-approval study in standard surgical risk patients following FDA approval of our PMA Supplement submission.

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, 2021, 2020 and 2019, our research, development and clinical expenses were $27.1 million, $21.3 million and $12.3 million, respectively.

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, Getinge / Maquet, Baxter, Terumo, Gore and Edwards. 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 include Abbott, Medtronic, Boston Scientific, and Cordis. Other companies have approved devices not currently marketed in the United States, including Gore, Terumo, Contego Medical and InspireMD. Additionally, some companies have stents and other products in ongoing IDE or planned IDE trials in the US, including Terumo and InspireMD. 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.

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;
- Availability 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, including direct-to-consumer advertising.

Finally, we may compete with medical device and pharmaceutical manufacturers outside the United States when we pursue plans to market our products internationally. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with healthcare professionals and greater name recognition in such markets.

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, 2021, we owned 112 patents globally, of which 69 were issued U.S. patents and 43 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, 2021, we had 76 pending patent applications globally, including 38 in the United States and 38 outside the United States.

As of December 31, 2021, 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 122 trademark registrations/ applications.

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 generally 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 and could prevent us from manufacturing, selling or using the product, any of which could severely harm our business.

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 at our approximately 31,000 square foot facility in Sunnyvale, California. This facility provides approximately 8,000 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. In May 2021, we entered into a lease for a 63,000 square foot facility in Plymouth, Minnesota which will provide approximately 21,000 square feet of additional space for our production and distribution operations, including manufacturing, quality control and storage. We expect to begin commercial production in the second half of 2022. We also have right of first refusal on the remaining 21,500 square feet of unleased space in the Plymouth, Minnesota facility. 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, and the European Medical Device Directive 93/42/EEC and amendments, or MDD, for medical devices marketed in the European Union. The new EU Medical Regulations took effect in May 2021, although our design examination certificates under the MDD remain valid until their expiration. Accordingly, we claim compliance with the EU MDR Article 120 and will be fully compliant with the EU MDR prior to the expiration of the current MDD certificates. 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 European Union Notified Body, British Standards Institute, or BSI, monitors compliance with the MDD requirements through both annual scheduled audits and periodic unannounced audits of our manufacturing facilities as well as our contract manufacturers' facilities.

Our failure, or the failure of our suppliers, to maintain acceptable quality requirements and compliance with all applicable healthcare laws and regulatory requirements could result in the shutdown or significant disruption of our manufacturing operations or the voluntary or involuntary recall of our products, which could harm our business. In the event that one of our suppliers fails to maintain acceptable quality requirements or regulatory compliance, we may have to qualify a new supplier and could experience a material adverse effect to manufacturing and manufacturing delays as a result. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by one of our third-party suppliers, Cordis Corporation, formerly a Cardinal Health Company, or 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. Recalls like this one could interrupt the delivery of our TCAR products to customers or may cause us to have to qualify a new supplier, either of which could cause our results of operations to be adversely impacted.

Our quality management system is ISO 13485 and MDD Certified. We have been an FDA registered medical device establishment and California licensed medical device manufacturer since 2011. We moved to our current Sunnyvale, California facility in June 2018, which was registered with the FDA in June 2018 and was issued a California device manufacturing license in August 2018. An ISO 13485 audit was conducted in September 2018 and our facility was recommended for certification.

The FDA conducted a total of five establishment inspections of our manufacturing facility in Sunnyvale, California in 2014, 2015, 2016 and 2020. A one-observation Form 483 Notice of Observation was issued in April 2015 relating to a transcription error in patient line listings and no additional follow up with the FDA was required. In February 2020, a one-observation Form 483 Notice of Observation was issued relating to the calibration method used for a specific type of measurement tool. In response, we initiated a Corrective and Preventive Action, or CAPA, and the Form 483 Notice of Observation was officially closed in June 2020. 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, BSI has conducted scheduled surveillance audits annually, recertification audits every third year, and periodic unannounced audits since the initial certification period starting in 2011 for compliance with ISO 13485 and MDD. The most recent recertification audit was conducted in November 2020, and no major non-conformities were identified. The most recent surveillance audit was conducted in October 2019, and no major non-conformities were identified. The most recent unannounced audit was conducted in July 2014, and no major non-conformities were identified. We believe that we are in compliance, in all material respects, with all ISO 13485 and MDD requirements.

Manufacturing of the materials and components of the ENROUTE NPS are provided by approved suppliers, all of which are single source suppliers of key components, sub-assemblies and materials. We purchase finished transcarotid access kit, guidewires 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 between one and two years to qualify a second source supplier for our ENROUTE stent. The suppliers for the ENROUTE NPS 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.

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. Both the 510(k) clearance 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 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 institutional review boards 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 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.

The 510(k) Approval 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 addition 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.

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 May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

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 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 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 are 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.

Pervasive and Continuing Regulation

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

- The FDA's QSR, which requires 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 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 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 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 Notified Body, BSI, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485 compliance in order to maintain our CE mark.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, 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 510 (k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- Withdrawing 510 (k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

European Union

Our portfolio of TCAR products is regulated in the European Union as a medical device per the European Union Directive 93/42/EEC, also known as the MDD. The MDD sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE mark is issued by BSI. Although the new EU Medical Regulations were effective in May 2021, our design examination certificates under the MDD remain valid until their expiration. Compliance with the EU MDR will be executed prior to the expiration of the current MDD certificates.

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.

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 these 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 FCA 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.

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 all pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children's Health Insurance Program to report annually to HHS: payments and transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Additionally, on October 24, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). Applicable manufacturers are required to submit annual reports to CMS. 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

In Europe, 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 CMS 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 imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began

on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. In December 2019, this excise tax was permanently repealed for medical device sales, effective after December 31, 2019. 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 2029 unless additional Congressional action is taken. 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

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 challenge 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 Conduct does more than just codify rules of conduct - it is the very foundation by which we conduct business every day. The Code of Conduct 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.

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.

Commitment to Diversity and Inclusion

At December 31, 2021, we had 352 employees, all located within the United States. 210 employees were engaged in marketing, sales, and administrative activities, 72 were engaged in research and development activities, and 70 were engaged in manufacturing operations. During 2021, the number of employees increased by 71. Our workforce consists of a highly skilled, diverse, and engaged team dedicated to the company's mission and goals. We are proud of the diversity in our organization with 39% of our organization ethnically diverse. In addition, women represented 48% of our organization. This ratio is consistent across leadership roles within the company, where women represent 50% of our people leaders and 50% of our executive leaders. We strive to create an inclusive work environment that represents the diversity in the communities where we live and work.

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 pipeline of diverse candidates through our Summer @ the Road internship program, through which 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.

We strive to create an inclusive work environment that represents the diversity in the communities we live and work.

Commitment to a Workplace Free of Discrimination and Harassment

In addition to our focus on our Cartwheel Culture, we strive to create a workplace that is free of bias, prejudice, discrimination and harassment. Our employment policies are designed to protect all employees, provide for their welfare and guide our behaviors and interactions. All managers and employees are required to take sexual harassment training as required by state laws. In 2022, we are adding a Managing within the Law course that will be offered to all managers. In short, we do not tolerate discrimination or harassment. We are also committed to maintaining a workplace free from harassment based on any protected characteristic.

Commitment to Equal Employment Opportunity

We are committed to maintaining a work environment in which all individuals are treated with respect and dignity. Everyone has the right to work in a professional atmosphere that promotes equal employment opportunities in all aspects of employment and personnel matters (including, without limitation, recruiting and hiring, job assignment, compensation, opportunities for advancement, evaluation, benefits, training, discipline, and termination), and prohibits discriminatory practices.

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 and we comply with all applicable health, safety and environmental laws as well as our Safety Programs. These Safety Programs and associated procedures have been developed and implemented throughout the company's facilities with employees' safety in mind. These programs include an Injury and Illness Prevention Program, an Emergency Action Plan, an Exposure Control Plan, a Hazard Communication Program and a Hazardous Waste Management Program. In addition, any employee working in a hospital operating room is required to wear a dosimetry badge that monitors occupational radiation exposure and compliance with annual limits.

In addition, the COVID-19 pandemic required us to redouble our commitment to employee safety while we ensured business continuity for our physician customers and their patients. We have accepted new ways of working and interacting and this has caused a shift in how we operate in our two office locations and in the hospitals in which we work. We maintain important safety protocols including requiring all employees to be vaccinated against the COVID-19 virus and providing for a hybrid work schedule for positions where that is possible. This shift required that we and every member of our company embrace a new way of working and put new energy into creating an office environment that is safe, healthy, and inspiring to work in.

Commitment to Competitive and Fair Compensation

We believe that employees should be compensated fairly for their contributions to the company. We practice paying competitive salaries and hourly wages. In order to ensure we pay our employees competitively, annual benchmarking is completed on all positions throughout the company. We use external benchmarking surveys to guide our assessment of compensation competitiveness. Each position is evaluated based on level of the role, the complexity of the position, and years of experience required. Our compensation program consists of the three primary components: base salary, annual bonus targets (non-sales), commission plans (sales), and equity. The Compensation Committee is responsible for our executive compensation programs for our executive officers and reports to our board of directors on its discussions, decisions and other actions. We also offer all employees the option to participate in our Employee Stock Purchase Plan (ESPP). Participants in the ESPP may purchase our 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 participating employees.

Commitment to the Health and Wellbeing of our Employees

Our top priorities are to maintain the health and wellbeing of our employees and their families. To achieve this goal, we offer a comprehensive employee benefits package with a variety of options. These programs include Medical, Dental, Vision, Life Insurance, Disability Programs, Retirement Programs including a match on the 401(k), Flexible Spending Accounts, Health Savings Accounts with a generous employer contribution, and an Employee Assistance Program. We pay 91% of healthcare premium costs on behalf of our employees. For new parents, we offer up to 160 hours of child bonding leave and provide a benefit for new moms who travel for business that allows for them to pump milk and ship it back home. In addition, we provide paid vacation and holiday time.

Commitment to Learning and Development

We believe that the professional development of our employees is a critical element to the success of our company. We are investing 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 people managers through a leadership development program that builds important leadership skills through online and live training programs. In addition, we provide training that builds knowledge on our product design, manufacturing process and also enhances skills on daily tasks including software tools and applications.

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. In 2021, with in-person volunteer activities limited due to COVID-19, we provided financial support to the American Heart Association, Meals on Wheels America, and Stroke Awareness Foundation. During the COVID-19 pandemic, we made a monetary and in-kind donation to the Valley Medical Foundation and a monetary donation to Meals on Wheels. We also used our logistics team to distribute PPE Equipment, including face masks, frocks, gloves, shoe covers, beard covers and hair nets donated by a third party to hospitals around the U.S.

Corporate and Other 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. 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. We encourage investors, our customers and others interested in our company to review the information we post on our Facebook page (https://www.facebook.com/SilkRoadMed/), LinkedIn page (https://linkedin.com/company/silk-road-med), and Twitter feed (https://twitter.com/SilkRoadMed). 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 Notes 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 described in Item 1A.

General Risks Related to Our Business

- Our business is dependent upon the continued adoption of TCAR by hospitals and physicians.
- Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.
- The COVID-19 pandemic and the spread of new variants continue to negatively impact our business and operations.
- We are experiencing inflationary pressures, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, which could increase our manufacturing costs and operating expenses and have a material adverse impact on our profitability and results of operations.
- If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or 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.
- 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 depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, 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 have a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.
- The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

Intellectual Property Risks

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

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

Regulatory Risks

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

Risks Related to Our Business

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

We have incurred net losses since our inception in March 2007. For the year ended December 31, 2021, we had a net loss of $49.8 million, and we expect to continue to incur additional losses in the future. As of December 31, 2021, we had an accumulated deficit of $288.7 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products that enable transcarotid artery revascularization. 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, expand the labeled indications for our products, conduct clinical studies, and develop additional products. In addition, as a public company, we incur significant legal, accounting, director & officer liability insurance and other expenses that we did not incur as a private company, all of which continue to increase. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

We rely on, and currently sell products to enable, TCAR, 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;
- 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 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; and
- Introduction of new products or procedures for treating carotid artery disease that compete with our products and the TCAR procedure.

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

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

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

Our future growth and profitability largely depends on our ability to increase physician awareness and adoption of TCAR and on the willingness of physicians to recommend the procedure to more of their patients. Physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery disease. Even if we are able to raise awareness and increase adoption of TCAR among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products or TCAR for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell other products, such as stents and embolic protection devices for transfemoral carotid artery stenting, or CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- 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.

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

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

relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

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

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

The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's Vascular Quality Initiative contains real world data retrospectively comparing carotid revascularization procedures including TCAR, we have not conducted 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 with best medical management solutions in standard surgical risk asymptomatic patients with carotid artery disease. Although we estimate that enrollment will not be completed until sometime after 2026, interim results have been released from time to time. At the completion of the four-year follow-up, the trial could conclude that medical management alone achieves the same 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, it generally discusses CAS and embolic protection methods, including flow reversal. The 2021 edition does 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 negative patient outcomes, affect adoption of TCAR and adversely affect our business.

The success of TCAR depends in part on the skill of the physician performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our ENROUTE NPS and proper deployment of our ENROUTE stent. However, physicians rely on their previous medical training and experience when performing TCAR, and we cannot guarantee that all such physicians will have the necessary surgical 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.

The COVID-19 pandemic and the spread of new variants continue to negatively impact our business and operations.

The spread of COVID-19 and its variants, or COVID-19, in the United States has continued to result in intermittent travel restrictions and restrictive hospital policies impacting our sales professionals and therapy development specialists who support them. New virus variants, including the Delta and Omicron variants, and increased infection and related hospitalization rates throughout the pandemic have increased the volatility and uncertainty in the number of TCAR procedures and demand for our products. Our field-based team continues to be available to support TCAR procedures, either in person or virtually. Members of our field team may, however, choose not to enter hospitals due to preexisting conditions, personal choice, or on doctors' orders or may be unable to enter hospitals due to hospital policy. In addition, hospitals have and continue to experience staffing shortages that cause problems scheduling or rescheduling TCAR procedures. Physicians or their patients may postpone TCAR procedures in response to COVID-19 or divert resources to treat patients with COVID-19 or other conditions deemed higher priority. Some hospitals have also restricted or limited access for non-patients, including our sales professionals and therapy development specialists, which has negatively impacted our access to physicians and their staff. Our business and operations may be impacted by competition for operating room and hybrid operating rooms within hospitals that have dedicated certain resources only to COVID-19 patients. As hospitals cancel and defer elective surgeries, it reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as they seek cost savings. Prolonged restrictions relating to COVID-19 could adversely affect our procedures and the revenue we derive as a result. Additionally, some hospitals may have cash flow problems or cease doing business due to the impact of COVID-19 on their operations, which could reduce the number of hospitals where TCAR is performed and adversely affect our ability to collect amounts due to us and our revenue as a result.

We expect these challenges to continue to impact the number of TCAR procedures for the foreseeable future, with procedure volumes impacted by increased COVID-19 hospitalizations and hospital capacity and staffing constraints due to recent COVID-19 variants. Patients may also be reluctant to visit their physicians at their offices or in hospitals due to fear of contracting COVID-19. Physicians may not be performing as many diagnostic tests for their patients and the labs where these tests are performed may not be open, staffed adequately or open the entire day. Even where physicians continue to treat symptomatic patients, treatment of asymptomatic patients is being deferred in many cases in areas where COVID-19 cases and hospitalizations are significant. The reduction in diagnostic testing and physician visits, the increase in deferred treatment, and patient behaviors are translating into fewer than expected TCAR procedures being performed in the current environment.

Governmental mandates related to COVID-19 or other infectious diseases have impacted, and we expect them to continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and/or reduce our margins. An extended implementation of governmental mandates could impact our ability to operate effectively and conduct ongoing manufacturing or research and development activities. However, we are considered an essential business under applicable state rules and our manufacturing operations are ongoing. If key personnel or large groups of our employees contract the virus, that may also impact our business and operations. In the meantime, we have taken steps to provide for our employees, including providing the ability for employees to work remotely and implementing strategies to support a safe work environment for onsite employees. In addition, we have required our employees to get the COVID-19 vaccine. We are also assessing our business continuity plans in the context of this pandemic. We have implemented distancing policies and protocols established to continue manufacturing and other operations.

The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion has delayed preparation for and launch of such expansion efforts. Regulatory timelines for approval in some countries have been delayed. Finally, we anticipate that the COVID-19 pandemic may continue to impact clinical and regulatory matters. COVID-19 is delaying enrollment in clinical trials across the medical device industry and may affect any new trials we decide to pursue. Additionally, we may experience regulatory delays in our effort to seek a label expansion for the ENROUTE stent in standard surgical risk patients, as the FDA has from time to time diverted resources to address the impact of COVID-19. COVID-19 may cause disruptions that could have a material adverse impact on our clinical trial plans and timelines, including:

- Delays in receiving authorizations from local regulatory authorities, ethics committees and institutional review boards to initiate planned clinical trials;
- Delays or difficulties in enrolling or follow up visits for patients in our clinical trials;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- Delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- Diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- Risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- 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;
- Limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- Refusal of the FDA to accept data from clinical trials in affected geographies.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the delay or denial of regulatory approvals or clearances of our product.

The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including the duration and severity of the pandemic, the actions taken to reduce the transmission of COVID-19 or mitigate the burden on hospitals, and the speed with which normal economic, labor market and operating conditions resume, among others.

COVID-19 has created global supply chain constraints and constrained labor markets, which could result in the inability of our suppliers to deliver components, sub-assemblies and materials to us on a timely basis or at all.

We are concerned about ensuring 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 used in both the ENROUTE stent and ENROUTE NPS are in short supply and delivery of these materials are likely to be delayed, which could result in manufacturing delays for our TCAR products. 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. In the event that any of our suppliers were to 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 were to experience a supply shortage with our components, sub-assemblies and the materials 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 are experiencing inflationary pressures, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, which could increase our manufacturing costs and operating expenses and have a material adverse impact on our profitability and results of operations.

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 pressure affecting the cost of the components for our TCAR products and in the wages that we pay our employees due to

challenging labor market conditions. Competitive 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 and other drivers of cost increases. As a result, we are unlikely to be able to pass these increased costs along to our customers or fully offset the impact of persistent inflation. 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.

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

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our manufacturing partners and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products would be negatively affected by many factors, including our rapid growth, product recalls, pandemics, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements and our manufacturing may be affected by the impact of COVID-19 on our suppliers. We have increased our inventory on hand in reaction to global supply chain constraints, but these inventory levels may prove to be inadequate. If we do not have adequate supply of components, sub-assemblies and materials there may be interruptions, delays or cancellations of deliveries of our TCAR products to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

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

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

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

If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or 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 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 process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. If third-party reimbursement is not available or adequate for 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 a National Coverage Determination, or NCD, for Percutaneous Transluminal Angioplasty. Coverage for non-Medicare patients depend upon commercial and other payer policies. Based on reimbursement information regarding CEA and CAS, we estimate that approximately 79% of carotid procedures are reimbursed by the U.S. Centers for Medicare & Medicaid Services, or CMS, and the remaining approximately 21% are reimbursed by commercial and other payers. Medicare is managed by CMS, which make the final determination regarding Medicare hospital and physician coverage and payment. Any future reconsideration of the applicable Medicare NCD may result in expansion of coverage of carotid stenting procedures including TCAR based on FDA-approved indications or continued coverage limitations to CMS approved CAS investigational studies. 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 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 policy changes to increase reimbursement for physician primary care services may result in reductions to physician payments for specialty services and procedures. 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.

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, 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. In August 2021, Cardinal Health divested Cordis to private equity firm Hellman & Friedman LLC. 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. If not extended, this license will expire on a country-by-country basis upon the expiration of all applicable Cordis patents – in certain countries, for example, our rights are expected to expire within the next few years. 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.

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 between us and Cordis Corporation. We strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, and we estimate that it would take one to two years to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for another stent, and in each case qualify it for use with our other products. In addition, Cordis currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. This facility has previously and in the future could become subject to a COVID-19 outbreak which would cause Cordis to temporarily shut down manufacturing operations, which would in turn present risk to the ongoing supply of our stents used in TCAR procedures. If Cordis's ability to manufacture the ENROUTE stent is interrupted as a result, or if Cordis experiences a product recall or breaches its supply agreement with us, we may not have a sufficient number of stents for delivery to support TCAR procedures. Finally, if not extended, our supply agreement with Cordis will terminate when our license agreement with Cordis terminates and we can provide no assurance that we will be able to negotiate or enter into a new supply agreement with Cordis on terms that are acceptable to us, or at all. We or Cordis may wish to re-evaluate certain aspects of the supply agreement we have with Cordis which may lead to lengthy or costly negotiations and affect our ability to obtain the ENROUTE stent at an acceptable price or at all. Any shortfall in the supply of ENROUTE stents may result in lower adoption rates for TCAR, fewer TCAR procedures being performed generally, and a material adverse effect on our business, financial condition and results of operations.

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

Risks of TCAR using our products include the risks that are common to 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. We are aware of certain characteristics and features of TCAR that may prevent widespread market adoption, including the fact that physicians would need to adopt a new procedure, and that training for physicians will be required to enable them to effectively operate our products.

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

intervention. Additionally, patients that lack at least five centimeters of common carotid artery free of significant disease are not indicated for our ENROUTE NPS.

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

Our business strategy depends on our ability to manufacture, 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 a facility located in Sunnyvale, California, where we currently assemble and package certain of our products, and inspect, release and ship all of our products, either directly to our customers or to our facility in Plymouth, Minnesota. We currently produce our ENROUTE NPS at our Sunnyvale facility, and we and the contract manufacturers of our other products do not currently have redundant facilities although we expect to begin manufacturing of our ENROUTE NPS at our Plymouth facility in the second half of 2022. 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 operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

We rely on single source suppliers for the components, sub-assemblies and materials for our products, such as our ENROUTE stent and for the key components, sub-assemblies and materials for our ENROUTE NPS**.** 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 rely on single source suppliers as well, and are subject to the foregoing risks.

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

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

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.

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

The total addressable market for TCAR is limited by a number of factors. Approximately 169,000 patients with carotid artery disease in the United States received treatment in the form of surgical or endovascular intervention in 2021. Of this group, we estimate that approximately one-third would be outside the scope of the FDA-approved labeling for the ENROUTE stent, as those patients are not deemed to be at high risk for adverse events from CEA, or high surgical risk. Although we have submitted a PMA supplement to the FDA to expand the labeling for the ENROUTE stent to treat

patients at standard risk for adverse events from CEA, the current FDA-approved labeling for the ENROUTE stent is limited to patients at high risk for adverse events from CEA. Patients at high risk for adverse events from CEA are defined as having significant comorbidities and/or anatomic risk factors, and/or advanced age, that would make them riskier candidates for CEA. Furthermore, the safety and effectiveness of 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 sheath. In addition, per the FDA-approved labeling for the ENROUTE stent, TCAR is limited to asymptomatic patients with carotid artery stenosis of at least 80% and symptomatic patients with carotid artery stenosis of at least 50%, both of which must also be high surgical risk. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions and severe vessel tortuosity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market.

Expanding the addressable market for TCAR is dependent upon labeling and reimbursement expansion initiatives.

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

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

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

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

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

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

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

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

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

We currently maintain our manufacturing and a portion of our 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, and we do not yet have redundant manufacturing although we expect to begin manufacturing of our ENROUTE NPS at our Plymouth facility in the second half of 2022. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and, with respect to certain products, approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage, 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, development and manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facilities could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments that are safer, more effective or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.

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

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

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

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

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

The market for our products is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with

ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We are currently focused on improving existing products for TCAR, developing new products for TCAR, and developing new products for other disease states beyond carotid artery disease. If we are unable to develop new products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

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

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

Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

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

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we

could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

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

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

Our future success depends upon patients having an experience with TCAR that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as arterial restenosis or dissection, cranial nerve injury, wound complications, transient ischemic attacks, stroke, heart attack, and death. If the results of TCAR do not meet the expectations of the patients, or patients experience adverse events, it could discourage patients from referring TCAR to others. For example, although we have not received any reports of strokes, deaths or other long-term patient sequelae from the tip detachments that triggered our recent recall, if there were to be patient injury, dissatisfied patients may express negative opinions through social media or we may otherwise suffer reputational damage or become subject to product liability lawsuits. Any failure to meet patient expectations and any resulting negative publicity or lawsuits could harm our reputation and future sales.

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

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

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

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

The ENROUTE stent has been approved by the FDA for the treatment of high surgical risk patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke, myocardial infarction and death, potentially leading to product liability claims. Our products are not indicated for use in all patients with carotid artery disease, and therefore cannot be marketed or advertised in the United States for certain uses without additional approvals or clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or

using components or products that are not our products when performing TCAR. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion.

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

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

Any growth that we experience in the future will require us to expand our sales, general and administrative personnel, manufacturing and distribution operations, and facilities and information technology 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.

Due to our recent growth in our business, we have leased additional space to provide offices, manufacturing and distribution operations and facilities for the employees we expect to hire in Plymouth, Minnesota and are also considering additional leased facilities in the San Francisco Bay Area. There is competition for office, shipping and warehousing space in the San Francisco Bay area and elsewhere and we can provide no assurance that we will find additional space or that such space will be on reasonable terms. If we are unable to obtain additional space or support on commercially reasonable terms our costs may go up or our business operations may be adversely affected.

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 and expected revenue will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of TCAR and our products;

- Whether we acquire third-party companies, products or technologies;
- Restructuring, refinancing or repayment of debt;
- The scope and timing of investment in our sales force, marketing initiatives and physician training programs;
- The scope, rate of progress and cost of our research and development activities, current or future clinical studies and additional regulatory clearances or approvals;
- The scope and timing of investment in acute ischemic stroke and other neurovascular and cardiac products we develop;
- The costs associated with any future product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights;
- The impact of COVID-19, including new variants, on our business and operations;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

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

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, and other operating restrictions that could adversely affect our ability to conduct our business.

In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

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

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

Our long-term strategy is to increase our international presence, including but not limited to securing regulatory approvals in Japan and China. We currently have the right to affix the CE Mark to our products, allowing us to commercialize in Europe in the future if we choose to do so. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international distributors, providers and payers. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;

- Obtaining regulatory clearance where required for our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Difficulties in adequately training and managing international distributors;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;
- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

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

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

We 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, 2021, we had an aggregate of approximately $49.0 million in principal outstanding under our Loan Agreement with Stifel Bank. We must make significant interest-only monthly payments under the Loan Agreement, which has diverted and will continue to divert resources from other activities. Our obligations under the Loan Agreement are collateralized by substantially all of our assets, excluding intellectual property, 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.

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, 2021, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $301.3 million and $254.5 million, respectively. Our U.S. federal NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2027 (U.S. federal NOLs arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028. We may use these NOLs to offset taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. 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. Although we have not performed a formal study under Section 382 of the Code, we believe we may have experienced at least one “ownership change” in the past and may have experienced others. 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, under the Tax Cuts and Jobs Act of 2017, although the treatment of U.S. federal NOLs arising in tax years beginning on or before December 31, 2017 has generally not changed, 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 federal income tax purposes in prior years.

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 and store sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of our other technology partners, may be vulnerable to cyber attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in

conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices with respect to our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

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

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of further enhancing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Moreover, in recent years, individuals and groups that are non-practicing entities 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 will depend on our ability to obtain, maintain and protect our intellectual property rights.

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

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

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

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

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

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

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

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

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands 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. 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.

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

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare

payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 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 the European Union and other countries where we may decide to commercialize could have similar effects.

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

Government payers, such as Centers for Medicare and Medicaid Services, or CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

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

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

- Federal and state laws and regulations regarding billing and claims payment applicable to TCAR and regulatory agencies enforcing those laws and regulations;
- FDA prohibitions against the advertisement, promotion and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- The federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the CMS programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties 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 manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to licensed physicians, certain other healthcare professionals, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Additionally, on October 24, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). 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;

- 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; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation, or GDPR, governing the privacy and security of health

information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

The growth of our business and sales organization and our 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.

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

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

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

Before a new medical device, including our recently FDA approved IDE for our feasibility study in acute ischemic stroke, Neuroprotection in Transcarotid Embolectomy (NITE-1), or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA's 510(k) clearance process usually takes from three to 12

months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at a minimum of 30 sites in the United States to evaluate the safety and effectiveness of our products in at least 600 subjects. We completed enrollment in this study and submitted our final report to the FDA. In February 2020 we received notice from the FDA of their review and that we have fulfilled the post-approval study requirement. A PMA supplement with the updated labeling was submitted to FDA in December 2019 and subsequently approved by FDA in June 2020. The updated labeling included outcomes and adverse event data from the ROADSTER 2 Post-Approval Study. Failure to have conducted the post-approval study in compliance with applicable regulations or to have timely completed required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new

products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites and facilities as part of its review process. As of February 28, 2022, we had filed 495 MDR reports with the FDA for adverse events and device malfunctions including, but not limited to, stroke, arterial dissection, tip detachment, stent thrombosis and wound complications.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to an additional inspection by, or increased scrutiny from, the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted.

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

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

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

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

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

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

Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

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

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

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

We are registered with the FDA as a medical device specifications developer, 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, and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

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

With the transition from the MDD to the new MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law, which was effective in May 2021. BSI, our notified body, successfully obtained designation to operate as conformity assessment authorities under the new law.

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

The European Union has released regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in-vitro diagnostics. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Major changes include:

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

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

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

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us 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 and harm our financial condition and results of operations. Additional recall announcements could also negatively affect our stock price.

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

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

Risks Related to Ownership of Our Common Stock

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

- The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:
- Changes in analysts’ estimates, investors’ perceptions, recommendations by securities analysts, the loss of analyst coverage or our failure to achieve analysts’ estimates;
- Quarterly variations in our or our competitors’ results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;

- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine;
- Changes in reimbursement by current or potential payers;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products, product enhancements or new product trials by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

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

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

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are required to comply with, among other requirements, the auditor attestation requirements of Section 404. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

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

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our

financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy our current and any future material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

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

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

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

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

Our amended and restated certificate of incorporation and bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against the company or any director or officer of the company arising pursuant to any provision of the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware or federal court located within the State of Delaware if the Court of Chancery does not have jurisdiction, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. A complaint asserting a cause of action under the Securities Act may be brought in state or federal court. With respect to the Securities Exchange Act of 1934, or Exchange Act, only claims brought derivatively under the Exchange Act would be subject to the forum selection clause described above. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated

certificate of incorporation and bylaws to be inapplicable or unenforceable in such action. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

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

Item 1B. Unresolved Staff Comments

None.

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 2024. 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.

In May 2021, we entered into a lease agreement for approximately 63,000 square feet of office space located in Plymouth, Minnesota 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 that the above facilities meet our current and future anticipated needs.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

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

Price Range of Common Stock

Our common stock began trading on the NASDAQ Global Select Market under the symbol "SILK" on April 4, 2019. Prior to that time, there was no public market for our common stock. In our initial public offering, our common stock priced at $20.00 per share on April 3, 2019. The following table sets forth on a per share basis, for the periods indicated, the low and high sale prices of our common stock as reported by the NASDAQ Global Select Market.

Year Ended December 31, 2021	High	Low
First Quarter	$ 62.70	$ 46.31
Second Quarter	$ 63.06	$ 44.66
Third Quarter	$ 65.80	$ 44.00
Fourth Quarter	$ 61.61	$ 39.32

Year Ended December 31, 2020	High	Low
First Quarter	$ 48.44	$ 20.84
Second Quarter	$ 44.50	$ 27.00
Third Quarter	$ 72.19	$ 41.93
Fourth Quarter	$ 75.80	$ 54.50

Holders of Record

At February 28, 2022, there were approximately 62 stockholders of record of our common stock, and the closing price per share of our common stock was $37.13. 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.

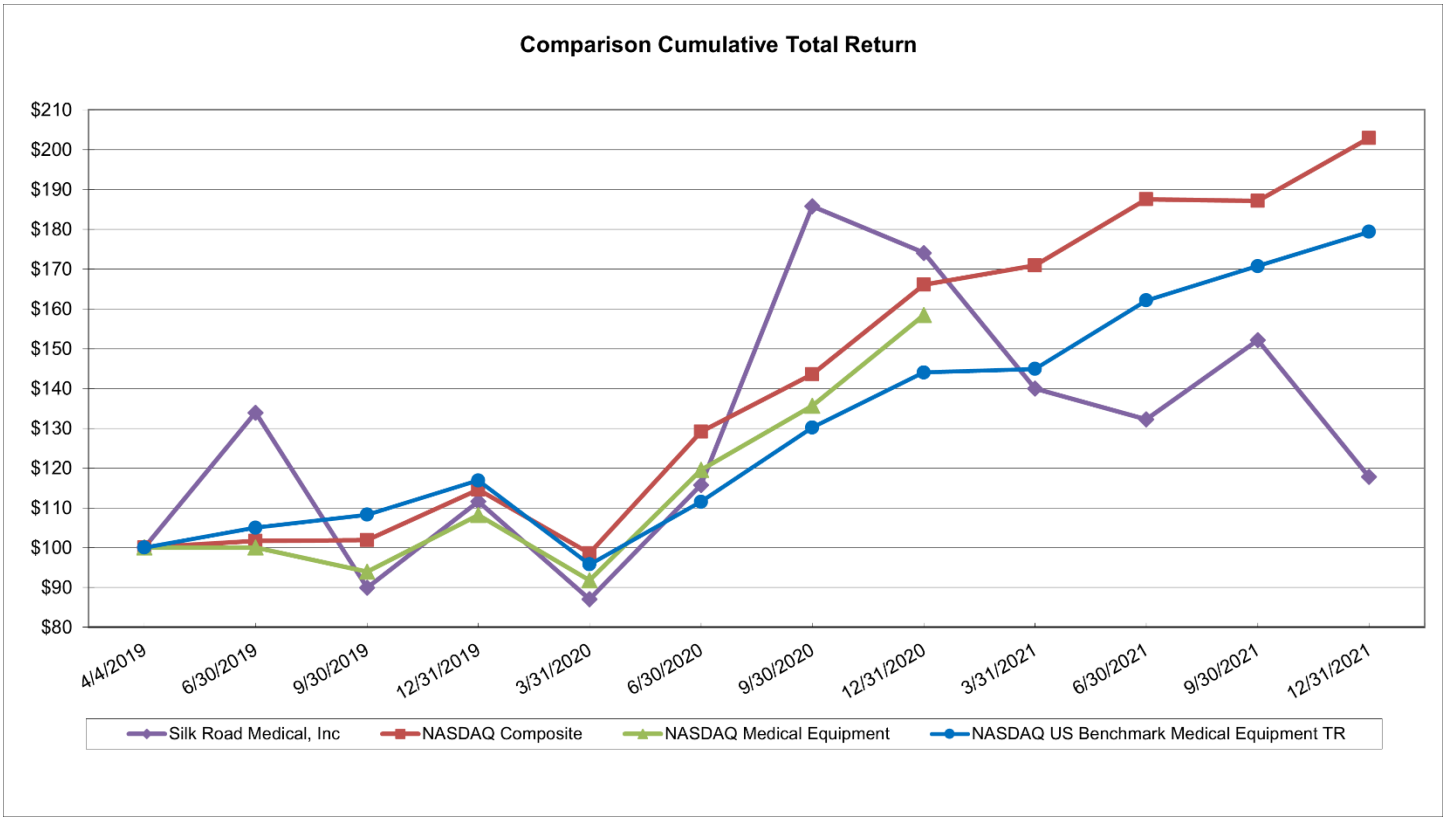
Securities Authorized for Issuance under Equity Compensation Plans

The information required by this Item 5 regarding equity compensation plans is incorporated by reference from the information under the captions "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" that will be contained in the Proxy Statement.

Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our 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, 2021. The NASDAQ U.S. Benchmark Medical Equipment TR Index replaces the NASDAQ Medical Equipment Index in this analysis going forward, as the CRSP Index data is no longer accessible. The CRSP index has been included with data through 2020.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
Silk Road Medical, Inc.(SILK)	$ 100	$ 134	$ 90	$ 112	$ 87	$ 116	$ 186	$ 174	$ 140	$ 132	$ 152	$ 118
NASDAQ Composite	$ 100	$ 102	$ 102	$ 115	$ 99	$ 129	$ 144	$ 166	$ 171	$ 188	$ 187	$ 203
NASDAQ Medical Equipment	$ 100	$ 100	$ 94	$ 108	$ 92	$ 120	$ 136	$ 158				
NASDAQ US Benchmark Medical Equipment TR	$ 100	$ 105	$ 108	$ 117	$ 96	$ 112	$ 130	$ 144	$ 145	$ 162	$ 171	$ 179

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Our initial public offering of 6,000,000 shares of common stock was effected through a registration statement on Form S-1 (File No. 333-230045), which was declared effective on April 3, 2019 and pursuant to which we sold an aggregate 6,000,000 shares of our common stock at a public offering price of $20.00 per share for an aggregate offering price of $120.0 million. On April 4, 2019, the underwriters fully exercised their option to purchase 900,000 additional shares of common stock from the selling stockholders pursuant to the underwriting agreement. When our initial public offering closed on April 8, 2019, we received net proceeds of $109.1 million, after deducting underwriting discounts and commissions of $8.4 million and other expenses of $2.5 million. No payments for such expenses were made directly or indirectly to any of our officers or directors or persons holding 10 percent or more of our securities.

J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated acted as representatives of the underwriters for the offering. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on April 4, 2019 pursuant to Rule 424(b) of the Securities Act.

In May 2020, we completed an underwritten public offering of 6,808,154 shares of common stock through a registration statement on Form S-3/ASR (File No. 333-238007), which was automatically effective upon filing on May 5,

2020. Pursuant to this registration statement we sold an aggregate 1,923,076 shares of our common stock at a public offering price of $39.00 per share for an aggregate offering price of $75.0 million, and certain selling stockholders sold an additional 4,885,078 shares of common stock. We received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions of approximately $3.8 million and offering costs of approximately $0.7 million. On May 20, 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders pursuant to the underwriting agreement. We did not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders.

J.P. Morgan Securities LLC and BofA Securities, Inc. acted as representatives of the underwriters for the offering. There has been no material change in the planned use of proceeds from the public offering as described in our final prospectus supplement filed with the SEC on May 7, 2020 pursuant to Rule 424(b) of the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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."

Overview

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

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

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

We currently manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We purchase our other products from third-party contract manufacturers, including our ENROUTE stent. Many of these third-party manufacturers and outside vendors are currently single-source suppliers. In May 2021, we entered into a lease for an additional facility in Plymouth, Minnesota. We expect to begin commercial production in the second half of 2022 and believe our combined facilities will be sufficient to meet our manufacturing needs for at least the next five years.

In April 2019, we completed our initial public offering by issuing 6,000,000 shares of common stock, at a public offering price of $20.00 per share, for net proceeds of approximately $109.1 million after deducting underwriting discounts and commissions and expenses. In August 2019, we completed a secondary public offering of 4,200,000 shares of common stock by selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of common stock from selling stockholders, at a public offering price of $39.50 per share. We received no proceeds from the sale of our common stock by the selling stockholders.

Prior to our initial public offering in April 2019, our primary sources of capital were private placements of convertible preferred stock, debt financing arrangements and revenue from sales of our products.

In May 2020, we completed an underwritten public offering of 6,808,154 shares of our common stock, of which we offered 1,923,076 shares for sale and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. From the public offering, we received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions and offering costs which were paid by us. Also, in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. We did not receive any of the proceeds from the sale of the shares of common stock by the

selling stockholders. As of December 31, 2021, we had cash and cash equivalents of $110.2 million, short-term debt of $3.9 million, long-term debt of $44.8 million and an accumulated deficit of $288.7 million.

COVID-19 Pandemic

The global COVID-19 pandemic presents significant risks to us and has had, and continues to have intermittent impacts on our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on: the health of our management and employees; our manufacturing, distribution, marketing and sales operations; our research and development activities, including clinical activities; and customer and patient behaviors. COVID-19 and its variants have negatively impacted, and may continue to negatively impact our operations and revenue and overall financial condition by significantly decreasing the number of TCAR procedures performed. The pandemic has also reduced our expectations for the growth rate in the number of TCAR procedures to be performed in the future. The number of TCAR procedures performed, similar to other surgical procedures, has significantly decreased as many health care organizations globally have prioritized the treatment of patients with COVID-19. In addition, hospitals have and continue to experience staffing shortages that cause problems scheduling or rescheduling TCAR procedures. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will significantly reduce our expected revenue while the pandemic continues. As well, due to presumed fear and anxiety, some patients are not accessing routine or emergency health care which may impact our expected procedures and revenue.

Governmental mandates related to COVID-19 or other infectious diseases have impacted, and we expect them to continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials. Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions have resulted in our facilities periodically closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. However, we are considered an essential business under applicable state rules and our manufacturing operations are ongoing.

Other disruptions or potential disruptions include intermittent restrictions on our personnel to travel and access customers for selling, marketing, training, case support and product development feedback; delays in approvals by regulatory bodies; delays in product development efforts; delays in preparation for and launch of our international expansion efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our products.

While some of these restrictions began to lift in 2021 and early 2022, new virus variants, and increased infection rates has continued to make the current COVID-related environment highly volatile and uncertain. The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, including the duration and severity of the pandemic, the actions taken to reduce the transmission of COVID-19 or mitigate the burden on hospitals, and the speed with which normal economic, labor market and operating conditions resume, among others. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

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 ENROUTE stent. No single customer accounted for 10% or more of our revenue during the during the years ended December 31, 2021, 2020 and 2019. We expect revenue to increase in absolute dollars as we expand our sales territories and trained physician base, add new accounts and as existing physicians perform more TCAR procedures. However, we anticipate continued headwinds related to the rapid spread of COVID-19 and its variants and their nearer term impact on hospital capacity, staffing challenges and patient behavior.

We expect our revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality. For example, in the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. Holiday and summer vacations by physicians and/or their patients can also affect procedure volumes that in turn affect hospital ordering patterns. We have also seen procedure volumes moderate during major medical conferences when significant portions of our customer base are attending the conferences.

Cost of Goods Sold and Gross Margin

We currently manufacture the ENROUTE NPS in California at our facility in Sunnyvale. We purchase our other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, direct labor, manufacturing overhead, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as those incurred for shipping our products and royalties related to the sale of our ENROUTE stent. We expense all inventory provisions as cost of goods sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, 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 any investments in additional operational infrastructure in both California and our new facility in Minnesota. We expect gross margin to be slightly lower for the year ended December 31, 2022, as we incur additional overhead related to our investment in the start-up and expansion of our manufacturing capacity in Minnesota. 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, due to the timing of certain manufacturing engineering projects, as we adopt new manufacturing processes and technologies and as we expand our distribution operations and infrastructure to support long term growth and risk mitigation. In addition, COVID-19 and its variants may continue to negatively impact our gross margin in the near term due to unfavorable production variances as a result of lower production and lower demand.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, medical affairs, and other costs associated with products and technologies that are in development. These expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. 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, we anticipate that the COVID-19 pandemic will continue to impact our product development efforts and clinical and regulatory matters for the foreseeable future. COVID-19 is delaying 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, due to additional legal, accounting, insurance and other expenses associated with being a public company, and as we expand our presence in Minnesota. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

While some of these restrictions began to lift throughout 2021 and allowed for the resumption in certain employee and physician travel, tradeshow and other expenses, due to new virus variants and increased infections, we expect the

COVID-19 pandemic to continue to modulate our SG&A expenses over the short term. The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion may also delay preparation for and launch of such expansion efforts.

Interest Income (Expense), net

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

Other Income (Expense), net

During the year ended December 31, 2019, other expense, net primarily consists of losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability at each balance sheet date. We had recorded adjustments to the estimated fair value of the convertible preferred stock warrants until they were exercised in connection with our initial public offering in April 2019. At such time, the final fair value of the warrant liability was reclassified to stockholders' equity and we no longer record any related periodic fair value adjustments.

(in thousands, except share and per share data)	Year Ended December 31,		
	2021	**2020**	**2019**
Revenue	$ 101,475	$ 75,227	$ 63,354
Cost of goods sold	25,446	21,291	15,927
Gross profit	76,029	53,936	47,427
Operating expenses:			
Research and development	27,110	21,271	12,272
Selling, general and administrative	96,387	75,524	63,220
Total operating expenses	123,497	96,795	75,492
Loss from operations	(47,468)	(42,859)	(28,065)
Interest income (expense), net	(2,320)	(3,307)	(3,296)
Loss on debt extinguishment	—	(1,119)	—
Other income (expense), net	(23)	(80)	(21,054)
Net loss	$ (49,811)	$ (47,365)	$ (52,415)

Comparison of Years Ended December 31, 2021 and 2020

Revenue. Revenue increased $26.2 million, or 35%, to $101.5 million during the year ended December 31, 2021, compared to $75.2 million during the year ended December 31, 2020. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures. Although revenue increased during the year ended December 31, 2021, as compared with the prior year, the COVID-19 pandemic continued to impact our revenue as resurgences due to the Delta and Omicron variants adversely effected hospital capacity and patient behaviors and presented staffing challenges. Revenue for the year ended December 31, 2020, included the recognition of $1.3 million in deferred revenue in the second quarter due to a decrease in the provision for sales returns. Excluding the contribution of the $1.3 million, revenue for the year ended December 31, 2021 increased $27.5 million, or 37%, compared to the year ended December 31, 2020. We do not anticipate future potential decreases in the sales return provision to materially impact subsequent quarters.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $4.2 million, or 20%, to $25.4 million during the year ended December 31, 2021, compared to $21.3 million during the year ended December 31, 2020. This increase was attributable to the increase in the number of products sold and also to additional overhead related to the start-up and expansion of our manufacturing capacity at our facility in Minnesota. Gross margin for the year ended December 31, 2021 increased to 75%, compared to 72% in the year ended December 31, 2020. Gross margin in the prior year period included unfavorable production variances as a result of temporarily idled manufacturing operations and lower than anticipated demand due to COVID-19, partially offset by the decrease in our provision for sales returns.

Research and Development Expenses. R&D expenses increased $5.8 million, or 27%, to $27.1 million during the year ended December 31, 2021, compared to $21.3 million during the year ended December 31, 2020. The increase in R&D expenses was driven by growth in personnel and investment in new and ongoing R&D programs. The increase in R&D expenses was primarily attributable to an increase of $6.6 million in personnel-related expenses, including stock-based compensation, as a result of increased headcount, an increase of $2.6 million in product development materials and costs, an increase of $0.8 million related to the allocation of facilities, depreciation and other related expenses, and

an increase of $0.6 million in outside services, partially offset by a decrease of $4.5 million in clinical and regulatory expense and a decrease of $0.3 million in educational grants. Clinical and regulatory expense in the prior year included costs attributable to our continued efforts to obtain label expansion of the ENROUTE stent in standard surgical risk patients.

Selling, General and Administrative Expenses. SG&A expenses increased $20.9 million, or 28%, to $96.4 million during the year ended December 31, 2021, compared to $75.5 million during the year ended December 31, 2020. The increase in SG&A costs was due to the continued expansion of our sales team and commercial efforts, and general corporate and other costs associated with operating as a public company, compared to the prior year period. The increase in SG&A expenses is primarily attributable to an increase of $17.2 million in payroll and personnel-related expenses, an increase of $2.2 million in physician training and travel related costs, an increase of $0.8 million in software related expense, an increase of $0.3 million in marketing and tradeshow expenses, an increase of $0.3 million related to the allocation of facilities, depreciation and other related expenses, and an increase of $0.2 million in insurance costs, partially offset by decreases in costs attributable to the COVID-19 pandemic. Personnel-related expenses included stock-based compensation expense of $11.1 million and $5.8 million for the years ended December 31, 2021 and 2020, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $1.0 million, or 30%, to an expense of $2.3 million during the year ended December 31, 2021, compared to an expense of $3.3 million during the year ended December 31, 2020. This decrease in net interest expense was attributable to the reduced interest rate as a result of the October 2020 refinancing of our debt obligations, partially offset by a decrease in interest income due to lower interest rates and lower cash, cash equivalents and investment balances during the year ended December 31, 2021 as compared with the prior year period.

Other Income (Expense), Net. There were no significant changes within other income (expense), net during the year ended December 31, 2021, compared to the year ended December 31, 2020.

Comparison of Years Ended December 31, 2020 and 2019

For a comparison of our results of operations for the fiscal years ended December 31, 2020 and 2019, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our annual report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 1, 2021.

Liquidity and Capital Resources

Sources of Liquidity

To date, our principal sources of liquidity have been the net proceeds we received through the sales of our common stock in our public offerings, private sales of our equity securities, payments received from customers using our TCAR products, and to a lesser extent the issuance of common stock through the exercise of stock options and our employee stock purchase program and proceeds from our debt financings. As of December 31, 2021, we had cash and cash equivalents of $110.2 million, an accumulated deficit of $288.7 million and $49.0 million outstanding principal under our Loan Agreement.

In April 2019, we completed our initial public offering by issuing 6,000,000 shares of common stock, at a public offering price of $20.00 per share, for net proceeds of approximately $109.1 million after deducting underwriting discounts and commissions and expenses. In August 2019, we completed a secondary public offering of 4,200,000 shares of common stock by selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of common stock from selling stockholders, at a public offering price of $39.50 per share. We received no proceeds from the sale of the common stock by the selling stockholders.

In May 2020, we completed an underwritten public offering of 6,808,154 shares of our common stock, of which we offered 1,923,076 shares for sale and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. From the public offering, we received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions and offering costs which were paid by us. Also, in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. We did not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders.

On October 29, 2020, we entered into a Loan and Security Agreement, or Loan Agreement, with Stifel Bank which provides for a $50.0 million loan facility, comprised of a $50.0 million secured revolving credit facility, with a $2.0 million subfacility for the issuance of letters of credit and other ancillary banking services, and a $50.0 million secured term loan facility, provided that amounts outstanding under both facilities may not exceed an aggregate principal amount of $50.0

million at any time. Any borrowings under the revolving loan facility mature on October 29, 2022, or October 29, 2023 if as of October 29, 2022, no event of default has occurred and we are in compliance with the terms of the Loan Agreement. Borrowings under the term loan facility mature on October 29, 2024. Also on October 29, 2020, we drew down $49.0 million under the term loan facility and used the majority of the proceeds to pay off and terminate our prior loan agreement with CRG.

We expect to continue to devote a substantial amount of our resources to expand commercialization efforts and increase adoption of TCAR using our products, improve and expand reimbursement for TCAR, expand the labeled indications for our products and develop additional products. We will continue exploring sales and marketing expansion opportunities in international geographies. In addition, as a public company, we incur significant legal, accounting, director & officer liability insurance, exchange listing and SEC compliance, investor relations and other expenses that we did not incur as a private company, 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 that our cash and cash equivalents as of December 31, 2021, together with our expected revenue, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months.

Cash Flows

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

	Years Ended December 31,		
(in thousands)	**2021**	**2020**	**2019**
Net cash (used in) provided by:			
Operating activities	$ (38,935)	$ (42,068)	$ (29,610)
Investing activities	72,644	(9,393)	(69,956)
Financing activities	6,978	81,746	113,757
Net increase in cash, cash equivalents and restricted cash	$ 40,687	$ 30,285	$ 14,191

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was $38.9 million, consisting primarily of a net loss of $49.8 million and an increase in net operating assets of $6.5 million, partially offset by non-cash charges of $17.4 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, decreases in accounts payable and other liabilities, due to timing of payments. These changes were partially offset by increases in accrued liabilities due to 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, depreciation and amortization, amortization of premiums on investments and of right-of-use assets, non-cash interest expense and provision for excess and obsolete inventories.

Net cash used in operating activities for the year ended December 31, 2020 was $42.1 million, consisting primarily of a net loss of $47.4 million and an increase in net operating assets of $5.2 million, partially offset by non-cash charges of $10.5 million. The increase in net operating assets was primarily due to increases in accounts receivable and inventories to support the growth of our operations and the repayment of paid in kind interest to CRG, partially offset by increases in accounts payable and accrued liabilities due to timing of payments and the growth of our operations. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, provision for excess and obsolete inventories, amortization of premiums on investments, non-cash interest expense and loss on debt extinguishment related to our term loan agreement with CRG.

Net cash used in operating activities for the year ended December 31, 2019 was $29.6 million, consisting primarily of a net loss of $52.4 million and a decrease in net operating assets of $3.0 million, partially offset by non-cash charges of $25.8 million. The decrease in net operating assets was primarily due to an increase in accounts receivable, inventories and prepaid expenses and other current assets to support the growth of our operations, partially offset by increases in accounts payable and accrued liabilities, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our term loan agreement, accretion of discounts on investments, and an increase in the fair value of the convertible preferred stock warrants.

Net Cash Used in Investing Activities

Net cash provided by investing activities in the year ended December 31, 2021 was $72.6 million. Cash provided by investing reflected maturities of investments of $77.4 million offset by purchases of property and equipment of $4.8 million.

Net cash used in investing activities in the year ended December 31, 2020 was $9.4 million. Cash used in investing reflected purchases of purchases of property and equipment of $0.8 million and net purchases of investments of $8.6 million.

Net cash used in investing activities in the year ended December 31, 2019 was $70.0 million consisting of purchases of available-for-sale investments of $69.4 million and purchases of property and equipment of $535,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the year ended December 31, 2021 was $7.0 million and primarily consisted of 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, 2020 was $81.7 million, consisting of proceeds of $70.6 million from our public offering in May 2020, net of issuance costs paid, proceeds from the issuance of debt of $48.5 million, net of issuance costs paid, and proceeds of $5.2 million from stock option exercises and purchases under our employee stock purchase plan, partially offset by repayment of debt of $40.0 million and $2.5 million in premiums paid on loss on extinguishment of debt.

Net cash provided by financing activities in the year ended December 31, 2019 was $113.8 million, primarily attributable to proceeds of $109.4 million from our initial public offering, net of issuance costs paid, proceeds of $2.6 million from stock option exercises and purchases under our employee stock purchase plan and warrant exercises of $1.8 million.

Term Loan Agreement

On October 29, 2020, we drew down $49.0 million under the term loan facility with Stifel Bank using the majority of the proceeds to pay off outstanding amounts under our loan agreement with CRG and to terminate the CRG loan agreement. The principal amount of outstanding term loans under the Loan Agreement with Stifel Bank shall be repaid in equal monthly installments beginning on November 29, 2022. The term loan may not be reborrowed once repaid, but we may prepay the term loan at any time without premium or penalty. We are also obligated to pay a fee to the lender upon the occurrence of certain liquidity events, along with other customary fees for a loan facility of this size and type. Assuming no event of default has occurred, and we are in compliance with the terms of the Loan Agreement, we intend to use the revolving credit facility to amortize the term loan obligations, effectively extending the interest-only period through October 2023. All principal amounts borrowed under the revolving credit facility will be due in October 2023. We would continue to pay the remaining monthly term loan obligations through October 2024.

Our obligations under the Loan Agreement are secured by substantially all of our assets. The Loan Agreement requires that we maintain unrestricted cash and cash equivalents with Stifel Bank or at Stifel Bank Affiliates of at least $20.0 million. In addition, for any fiscal quarter where our unrestricted cash and cash equivalents maintained with Stifel Bank or at Stifel Bank Affiliates are less than $60.0 million for any day during such fiscal quarter, we must comply with a minimum revenue covenant. 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, 2021, the aggregate outstanding principal balance under the Loan Agreement was $49.0 million. As of the date of this Annual Report on Form 10-K, we were in compliance with all covenants under the term loan agreement.

Cordis License Agreement

In December 2010, we entered into a license agreement, or the Cordis License Agreement, with Cordis Corporation, or Cordis. Pursuant to the Cordis License Agreement, Cordis granted us a worldwide, non-exclusive, 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.

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 on a country-by-country basis until the last to expire of the Licensed IP in such country.

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, or Cordis Supply Agreement, with Cordis and have since entered into four amendments in March and July 2012, April 2013 and April 2018. 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, has supplied the ENROUTE stent through preclinical and clinical trials, and continues to supply the ENROUTE stent for our commercial sale. 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.

We are obligated under the Cordis Supply Agreement to purchase a minimum volume of the ENROUTE stent annually. This obligation is binding until the natural expiration of the Cordis License Agreement, due to expiration of the last-to-expire of the Licensed IP, if the Cordis License Agreement remains in effect through such natural expiration.

Cordis has the exclusive right to manufacture and supply the ENROUTE stent during the term of the Cordis Supply Agreement. However, 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. Notwithstanding the foregoing, we, without Cordis' consent, may work directly with Confluent for the development and supply of next-generation products that materially expand or change the specification of the ENROUTE stent.

Lease Agreements

We currently lease our headquarters in Sunnyvale, California pursuant to a lease agreement which terminates in October 2024. 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. The facility lease is for approximately 31,000 square feet.

In May 2021, we entered into a lease agreement for a 63,000 square foot facility in Plymouth, Minnesota 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.

Contractual Obligations and Commitments

Our principal obligations consist of the operating lease for our facilities, our Loan Agreement with Stifel Bank and non-cancellable inventory purchase commitments. The following table sets out, as of December 31, 2021, our contractual obligations and commitments due by period:

	Payments Due by Period				
(in thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years	Total
Operating lease obligations	$ 1,471	$ 3,731	$ 1,786	$ 2,769	$ 9,757
Loan agreement with Stifel Bank	3,905	45,095	—	—	49,000
Non-cancellable purchase commitments	4,631	1,030	—	—	5,661
Other long-term obligations	671	76	—	—	747
	$ 10,678	$ 49,932	$ 1,786	$ 2,769	$ 65,165

The non-cancellable purchase commitments primarily consist of ENROUTE stents and other inventory components.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

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 policies, which are those that are 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. 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 and foreign currency exchange rate sensitivity.

Interest Rate Risk

We had cash and cash equivalents of $110.2 million as of December 31, 2021 which consisted of bank deposits and money market funds.

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 as of December 31, 2021.

Credit Risk

As of December 31, 2021 and 2020, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are in excess of insured limits. We have reviewed the financial statements of these institutions and believe each to have sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. As of December 31, 2021, our cash equivalents are invested in highly rated money market funds.

Our accounts receivable primarily relate to revenue from the sale of our products to hospitals and medical centers in the United States. No customer represented 10% or more of our accounts receivable as of December 31, 2021 or 2020.

Foreign Currency Risk

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

Item 8. Financial Statements and Supplementary Data

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, 2021 and 2020, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit), and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes and financial statement schedule 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, 2021, 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, 2021 and 2020**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 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, 2021, 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 under the Company's standard terms and conditions. The Company's total revenue was $101.5 million for the year ended December 31, 2021. 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) testing 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 iv) testing the completeness and accuracy of data provided by management.

/s/PricewaterhouseCoopers LLP
San Jose, California
March 1, 2022

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 110,231	$ 69,466
Short-term investments	—	78,016
Accounts receivable, net of allowances of $6 and $13 at December 31, 2021 and December 31, 2020, respectively	11,832	9,070
Inventories	17,851	9,989
Prepaid expenses and other current assets	3,412	6,787
Total current assets	143,326	173,328
Property and equipment, net	7,697	2,844
Restricted cash	232	310
Other non-current assets	5,370	2,832
Total assets	$ 156,625	$ 179,314
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	2,379	2,598
Accrued liabilities	19,802	16,957
Short-term debt	3,905	—
Total current liabilities	26,086	19,555
Long-term debt	44,786	48,533
Other liabilities	6,513	3,726
Total liabilities	77,385	71,814
Commitments and contingencies (Note 7)	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 at December 31, 2021 and 2020		
Shares issued and outstanding: none at December 31, 2021 and 2020	—	—
Common stock, $0.001 par value		
Shares authorized: 100,000,000 at December 31, 2021 and 2020		
Shares issued and outstanding: 34,980,896 and 34,249,649 at December 31, 2021 and 2020, respectively	35	34
Additional paid-in capital	367,907	346,318
Accumulated other comprehensive income	—	39
Accumulated deficit	(288,702)	(238,891)
Total stockholders' equity	79,240	107,500
Total liabilities and stockholders' equity	$ 156,625	$ 179,314

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,		
	2021	**2020**	**2019**
Revenue	$ 101,475	$ 75,227	$ 63,354
Cost of goods sold	25,446	21,291	15,927
Gross profit	76,029	53,936	47,427
Operating expenses:			
Research and development	27,110	21,271	12,272
Selling, general and administrative	96,387	75,524	63,220
Total operating expenses	123,497	96,795	75,492
Loss from operations	(47,468)	(42,859)	(28,065)
Interest income	198	1,104	1,656
Interest expense	(2,518)	(4,411)	(4,952)
Loss on debt extinguishment	—	(1,119)	—
Other income (expense), net	(23)	(80)	(21,054)
Net loss	(49,811)	(47,365)	(52,415)
Other comprehensive loss:			
Change in unrealized gain (loss) on investments, net	(39)	37	2
Net change in other comprehensive loss	(39)	37	2
Net loss and comprehensive loss	$ (49,850)	$ (47,328)	$ (52,413)
Net loss per share, basic and diluted	$ (1.44)	$ (1.44)	$ (2.28)
Weighted average common shares used to compute net loss per share, basic and diluted	34,635,358	32,965,539	22,956,679

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

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

(in thousands, except share data)	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	21,233,190	$ 105,235	1,135,310	$ 1	$ 4,557	$ (139,111)	$ —	$ (134,553)
Exercise of Series C preferred stock warrants	292,361	1,784	—	—	—	—	—	—
Exercise of common stock warrants	—	—	3,764	—	31	—	—	31
Issuance of common stock in connection with IPO, net of underwriting discount, commissions and offering costs of $10,961	—	—	6,000,000	6	109,113	—	—	109,119
Conversion of preferred stock to common stock upon IPO	(23,178,555)	(144,140)	23,178,555	23	144,117	—	—	144,140
Net exercise of Series C preferred stock warrants upon IPO	1,653,004	37,121	—	—	—	—	—	—
Net exercise of common stock warrants upon IPO	—	—	2,204	—	—	—	—	—
Exercise of stock options	—	—	873,786	1	1,541	—	—	1,542
Issuance of common stock under employee stock purchase plan	—	—	61,648	—	1,048	—	—	1,048
Stock-based compensation	—	—	—	—	2,977	—	—	2,977
Net loss	—	—	—	—	—	(52,415)	—	(52,415)
Change in unrealized gains on investments, net	—	—	—	—	—	—	2	2
Balances at December 31, 2019	—	—	31,255,267	31	263,384	(191,526)	2	71,891
Issuance of common stock in connection with public offering, net of underwriting discount, commissions and offering costs of $4,457	—	—	1,923,076	2	70,541	—	—	70,543
Exercise of stock options	—	—	1,018,779	1	3,486	—	—	3,487
Issuance of common stock under employee stock purchase plan	—	—	52,527	—	1,681	—	—	1,681
Stock-based compensation	—	—	—	—	7,226	—	—	7,226
Net loss	—	—	—	—	—	(47,365)	—	(47,365)
Change in unrealized gains on investments, net	—	—	—	—	—	—	37	37
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 release 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

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,		
	2021	2020	2019
Cash flows from operating activities			
Net loss	$ (49,811)	$ (47,365)	$ (52,415)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,032	789	712
Stock-based compensation expense	14,612	7,226	2,977
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	21,030
Amortization of premiums (accretion of discounts) on investments, net	577	304	(309)
Amortization of debt discount and debt issuance costs	158	66	46
Amortization of right-of-use asset	887	602	582
Non-cash interest expense	—	241	672
Loss on extinguishment of debt	—	1,119	—
Loss on disposal of property and equipment	9	52	—
Change in provision for doubtful accounts receivable	6	(32)	23
Provision for excess and obsolete inventories	77	117	118
Changes in operating assets and liabilities:			
Accounts receivable	(2,769)	(437)	(2,241)
Inventories	(5,563)	(2,161)	(4,696)
Prepaid expenses and other current assets	(772)	250	(1,471)
Other assets	(117)	210	552
Accounts payable	(1,159)	592	615
Accrued liabilities	4,418	146	4,964
Other liabilities	(520)	26	(769)
Repayment of interest paid in kind	—	(3,813)	—
Net cash used in operating activities	(38,935)	(42,068)	(29,610)
Cash flows from investing activities			
Purchases of property and equipment	(4,758)	(842)	(535)
Proceeds from sale of property and equipment	2	—	—
Purchases of investments	—	(79,906)	(69,421)
Proceeds from maturity of investments	77,400	71,355	—
Net cash provided by (used in) investing activities	72,644	(9,393)	(69,956)
Cash flows from financing activities			
Proceeds from public offerings, net of underwriting discount, commissions and offering costs paid	—	70,568	109,352
Proceeds from long-term debt, net	—	48,506	—
Proceeds from issuance of common stock	6,946	5,168	2,590
Proceeds from exercise of redeemable convertible preferred stock warrants	—	—	1,784
Proceeds from exercise of common stock warrants	—	—	31
Principal repayment of long-term debt	—	(40,000)	—
Payments of prepayment penalty and lender fees	—	(2,496)	—
Proceeds from disgorgement of short-swing profits, net	32	—	—
Net cash provided by financing activities	6,978	81,746	113,757
Net change in cash, cash equivalents and restricted cash	40,687	30,285	14,191
Cash, cash equivalents and restricted cash, beginning of year	69,776	39,491	25,300
Cash, cash equivalents and restricted cash, end of year	$ 110,463	$ 69,776	$ 39,491
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 2,360	$ 7,917	$ 4,234
Noncash investing and financing activities:			
Accounts payable and accrued liabilities for purchases of property and equipment	$ 1,138	$ 108	$ 32
Unpaid deferred offering costs	$ —	$ 25	$ —
Right-of-use asset obtained in exchange for lease obligation	$ 3,307	$ —	$ 3,982
Net exercise of convertible preferred stock warrants to preferred stock	$ —	$ —	$ 37,121
Conversion of convertible preferred stock to common stock upon initial public offering	$ —	$ —	$ 144,140

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

1. Formation and Business of the Company

The Company

Silk Road Medical, Inc. (the "Company") was incorporated in the state of Delaware on March 21, 2007. The Company has developed a technologically advanced, minimally-invasive solution for patients with carotid artery disease who are at risk for stroke. The Company's portfolio of TCAR products enable a new procedure, referred to as transcarotid artery revascularization, or TCAR, that combines the benefits of endovascular techniques and surgical principles. The Company manufactures and sells in the United States its portfolio of TCAR products which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. The Company commercialized its products in the United States in 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, 2021, the Company had an accumulated deficit of $288,702,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $110,231,000 at December 31, 2021, as well as its expected revenues will provide sufficient funds to allow the Company to fund its planned current operations for the next twelve months from the issuance of these financial statements.

Reverse Stock Split

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

Public Offerings

In April 2019, the Company issued and sold 6,000,000 shares of its common stock in its IPO at a public offering price of $20.00 per share, for net proceeds of approximately $109,119,000 after deducting underwriting discounts and commissions of approximately $8,400,000 and expenses of approximately $2,481,000. Upon the closing of the IPO, all shares of redeemable convertible preferred stock then outstanding converted into shares of common stock and the Company's outstanding warrants to purchase shares of common and redeemable convertible preferred stock were exercised, or automatically net exercised absent a prior election. The exercises resulted in the reclassification of the fair value of the related redeemable convertible preferred stock warrant liability to additional paid-in capital.

In August 2019, the Company completed a secondary public offering of 4,200,000 shares of its common stock sold by certain selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of its common stock from certain selling stockholders, at a public offering price of $39.50 per share. The Company did not receive any of the proceeds from the sale of the shares of its common stock from the selling stockholders.

In May 2020, the Company completed an underwritten public offering of 6,808,154 shares of its common stock, of which 1,923,076 shares were offered for sale by the Company and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. The Company received cash proceeds of approximately $70,543,000 after deducting underwriting discounts and commissions of approximately $3,750,000 and expenses of approximately $707,000. Also, in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. The Company did not receive any of the proceeds from the sale of the shares of its common stock by the selling stockholders.

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 ("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, stock-based compensation, and for periods prior to the Company's IPO, the valuation of common stock and redeemable convertible preferred stock warrants. 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.

Due to the coronavirus ("COVID-19") pandemic, there has been continued uncertainty and disruption in the global economy, supply chain, financial markets and increased labor shortages. While some of the uncertainties began to lift throughout the first half of 2021, new virus variants, and increased infection rates during the second half of 2021 continue to make the current COVID-related environment highly volatile and uncertain. These challenges continued to impact the number of TCAR procedures in 2021, with procedure volumes impacted by increased COVID-19 hospitalizations and hospital capacity constraints due to the COVID-19 and its variants. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments or a revision of the carrying value of its assets or liabilities as of December 31, 2021. The Company has also considered information available to it as of the date of issuance of these financial statements and is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. Actual results could differ materially from these estimates.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2021 and 2020. The carrying amounts of certain of the Company's financial instruments, which include cash equivalents, short-term investments, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these instruments. Management believes that its short-term and long-term 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. Prior to the Company's IPO, fair value accounting was applied to the redeemable convertible preferred stock warrant liability.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of December 31, 2021, the Company's cash equivalents are comprised of investments in money market funds. As of December 31, 2020, the Company's cash equivalents comprised investments in money market funds and commercial paper.

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,	
	2021	2020
Cash and cash equivalents	$ 110,231	$ 69,466
Restricted cash	232	310
Total cash, cash equivalents and restricted cash	$ 110,463	$ 69,776

Restricted cash as of December 31, 2021 and 2020 consists of a letter of credit of $232,000 and $310,000, respectively, representing collateral for the Company's facility lease in California.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have original maturities greater than 90 days, but less than one year as of the balance sheet date. Long-term investments have maturities greater than one

year as of the balance sheet date. All investments are recorded at fair value based on the fair value hierarchy. Money market funds are classified within Level 1 of the fair value hierarchy, and commercial paper, corporate bonds/notes, United States Government securities, and asset-backed securities are classified within Level 2 of the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss). The cost of available-for-sale investments sold is based on the specific-identification method. Realized gains and losses are included in earnings and are derived for specific-identification method for determining the costs of investments sold and were insignificant for the year ended December 31, 2021, 2020 and 2019. 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.

Concentration of Credit Risk, and Other Risks and Uncertainties

The Company is subject to risks related to public health crises such as the global pandemic associated with COVID-19. The COVID-19 outbreak has negatively impacted, and may continue to negatively impact the Company's operations, its revenue and overall financial condition by significantly decreasing the number of TCAR procedures performed. The number of TCAR procedures performed, similar to other surgical procedures, has significantly decreased as health care organizations globally prioritized the treatment of patients with COVID-19. In the past governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled to focus limited resources and personnel and hospital capacity toward the treatment of COVID-19 and to avoid exposing patients to COVID-19. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to negatively impact the Company's revenue while the pandemic continues. New virus variants, and increased infection rates continue to make the current COVID-related environment highly volatile and uncertain.

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, United States Government securities, asset-backed securities 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, 2021 and 2020.

The Company's accounts receivable are due from a variety of health care organizations in the United States. At December 31, 2021 and 2020, no customer represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2021, 2020 and 2019, there were no customers that represented 10% or more of revenue.

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

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

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

Existing or future devices developed by the Company may require approvals or clearances from the 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.

Voluntary Recall

In January and February 2021, the Company announced the voluntary recall of certain lots of its ENROUTE Transcarotid Stent System, manufactured by one of its third-party suppliers, Cordis. The decision to recall these lots was based on complaints received about tips detaching from the stent delivery system as well as internal testing that the Company conducted. The Company believes 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.

As a result of the voluntary recall the Company reflected a current asset of $4,160,000 on its balance sheet as of December 31, 2020, relating to the replacement lots and other direct costs to be received from Cordis. This amount included $2,227,000 of recalled ENROUTE stent delivery systems held in the Company's inventory as of December 31, 2020, $1,696,000 of ENROUTE stent delivery systems in the process of being returned from its customers and other direct costs of $237,000. In addition, the Company established an accrual of $1,696,000 relating to its obligation to provide replacement ENROUTE stent delivery systems to its customers as of December 31, 2020. As of December 31, 2021, the Company has a current asset of $335,000 on its balance sheet relating to other direct costs that remain to be reimbursed from Cordis. In addition, as of December 31, 2021, the Company has a remaining accrual of $11,000 relating to its obligation to provide replacement ENROUTE stent delivery systems to its customers.

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, 2021, 2020 and 2019, 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.

Other Current Assets

The prepaid expenses and other current assets balance at December 31, 2020 included $4,160,000 associated with the Company's voluntary recall. The amount relates to the replacement lots and other direct costs to be received from Cordis. As of December 31, 2021, the Company has a current asset of $335,000 on its balance sheet relating to other direct costs that remain to be reimbursed from Cordis.

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, 2021, 2020 and 2019.

Leases

The Company accounts for its leasing arrangements in accordance with Accounting Standards Codification ("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.

Redeemable Convertible Preferred Stock Warrant Liability

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

Redeemable Convertible Preferred Stock

Prior to its IPO, the Company recorded its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs, and classified the redeemable convertible preferred stock outside of stockholders' equity on the balance sheet as events triggering the liquidation preferences were not solely within the Company's control. Upon the closing of the Company's IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 23,178,555 shares of common stock resulting in the reclassification of $144,140,000 from outside of stockholders' equity to additional paid-in capital.

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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

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

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

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

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

As of December 31, 2021 and 2020, the Company recorded $87,000 and $71,000, 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's revenue is generated from the sale of its products to hospitals and medical centers in the United States through direct sales representatives. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company's products to its customers, either upon shipment of the product or delivery of the product to the customer under the Company's standard terms and conditions. The Company's products are readily available for usage as soon as the customer possesses it. Upon receipt, the customer controls the economic benefits of the product, has significant risks and rewards, and the legal title. The Company has present right to payment; therefore, the transfer of control is deemed to happen at a point in time. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring the goods.

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

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

Costs associated with product sales include commissions and royalties. The Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of 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 our 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 facility 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, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalties. In May 2021, the Company entered into a lease for an additional facility in Minnesota and expects to begin

commercial production in the second half of 2022. During this time the Company experienced additional overhead related to manufacturing start-up and expansion of its manufacturing capacity, 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, research and development expenses include costs associated with our clinical studies including 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 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 $221,000, $194,000 and $362,000 were expensed during the years ended December 31, 2021, 2020 and 2019, 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, 2021, 2020 and 2019.

Stock–Based Compensation

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") ASC 718, "Compensation-Stock Compensation." ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options, restricted 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. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions. The Company accounts for option forfeitures as they occur.

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

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, 2021, 2020 and 2019, 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 income. Accumulated other comprehensive 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, redeemable convertible preferred stock and warrants, common stock options, and restricted 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.

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

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

	Year Ended December 31,		
	2021	2020	2019
Net loss	$ (49,811)	$ (47,365)	$ (52,415)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	34,635,358	32,965,539	22,956,679
Net loss per share, basic and diluted	$ (1.44)	$ (1.44)	$ (2.28)

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,		
	2021	2020	2019
Common stock options	3,780,939	4,237,828	4,310,790
Restricted stock units	530,274	68,396	—
Total	4,311,213	4,306,224	4,310,790

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, 2021, 2020 and 2019, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

Recently Adopted Accounting Standards

Effective January 1, 2021, the Company adopted ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for most financial assets and certain other instruments. In addition, Topic 326 also provides new guidance related to the measurement of expected credit losses on the Company's allowance for bad debt for accounts receivable, which is estimated upon assessment of various factors including historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of the Company's customers. The Company adopted the new standard using a modified retrospective transition method, which required a cumulative-effect adjustment, if any, to the opening balance of accumulated deficit to be recognized on the date of adoption. The Company did not have any cumulative-effect adjustments as of the date of adoption.

Effective January 1, 2021, the Company adopted ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which enhances and simplifies various aspects of the income tax accounting guidance related to intra-period tax allocation, interim period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim period tax accounting. ASU 2019-12 also amends other aspects of the guidance to reduce complexity in certain areas. The adoption did not have a material impact on the Company's financial statements and related disclosures.

Recently Issued Accounting Standards

In October 2021, the FASB issued ASU No. 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers ("ASU 2021-08"), which creates an exception to the general recognition and measurement principle in ASC 805 by requiring companies to apply ASC 606 to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. The guidance additionally clarifies that companies should apply the definition of a performance obligation in ASC 606 when recognizing contract liabilities assumed in a business combination. The Company will early adopt ASU 2021-08 as of January 1, 2022 on a prospective basis. The impact of the adoption of ASU 2021-08 cannot currently be determined, as it is dependent on future business combinations that the Company may enter into.

4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, investments, and the Company's previously outstanding preferred stock warrants. 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 quotes prizes 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 cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The corporate bonds/notes, commercial paper, asset-backed securities and U.S. government securities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques 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 table sets forth by level within the fair value hierarchy the Company's assets and liabilities that are reported at fair value as of December 31, 2021 and 2020 using the inputs defined above (in thousands):

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 21,062	$ —	$ —	$ 21,062
	$ 21,062	$ —	$ —	$ 21,062

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 60,295	$ —	$ —	$ 60,295
Commercial paper	—	39,577	—	39,577
Corporate bonds/notes	—	7,969	—	7,969
U.S. government securities	—	38,470	—	38,470
	$ 60,295	$ 86,016	$ —	$ 146,311

There were no transfers between fair value hierarchy levels during the years ended December 31, 2021 and 2020.

5. Balance Sheet Components

Investments

The Company's cash equivalents consists of $21,062,000 in money market funds as of December 31, 2021 and approximates fair value. The Company had no investments as of December 31, 2021. The fair value of the Company's available-for-sale investments as of December 31, 2020 are as follows (in thousands):

	December 31, 2020			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 60,295	$ —	$ —	$ 60,295
Commercial paper	39,577	—	—	39,577
Corporate bonds/notes	7,970	—	(1)	7,969
U.S. government securities	38,430	42	(2)	38,470
	$ 146,272	$ 42	$ (3)	$ 146,311
Classified as:				
Cash equivalents				$ 68,295
Short-term investments				78,016
				$ 146,311

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, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Amounts maturing within one year	$ 21,062	$ 146,311
Amounts maturing after one year through two years	—	—
	$ 21,062	$ 146,311

The following table presents the Company's available-for-sale investments that were in an unrealized loss position as of December 31, 2020 (in thousands):

	December 31, 2020	
	Less than 12 months	
Assets:	**Fair Value**	**Unrealized Loss**
Corporate bonds/notes	$ 5,369	$ (1)
U.S. government securities	10,128	(2)
	$ 15,497	$ (3)

Inventories

Components of inventories were as follows (in thousands):

	December 31,	
	2021	**2020**
Raw materials	$ 2,447	$ 1,785
Finished products	15,437	10,599
	17,884	12,384
Less: Reserve for excess and obsolete	(33)	(2,395)
	$ 17,851	$ 9,989

As of December 31, 2021 and 2020, there were no work-in-process inventories. The reserve for excess and obsolete inventory at December 31, 2021 and 2020 included $1,000 and $2,377,000, respectively, associated with the Company's voluntary product recall.

Property and Equipment, Net

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

	December 31,	
	2021	**2020**
Furniture and fixtures	$ 1,005	$ 726
Equipment	2,945	1,699
Software	284	226
Leasehold improvements	2,050	2,043
	6,284	4,694
Less: Accumulated depreciation	(3,330)	(2,332)
Add: Construction-in-progress	4,743	482
	$ 7,697	$ 2,844

Depreciation and amortization expense was $1,032,000, $789,000 and $712,000 for the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued payroll and related expenses	$ 13,898	$ 9,573
Provision for sales returns	359	820
Accrued professional services	2,039	2,520
Recall replacement obligation	11	1,696
Operating lease liability	1,294	850
Accrued royalty expense	687	518
Deferred revenue	157	206
Accrued travel expenses	590	237
Accrued clinical expenses	99	113
Accrued other expenses	668	424
	$ 19,802	$ 16,957

6. Debt

CRG

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

In September 2018, the term loan agreement was amended to provide for additional term loans in an aggregate principal amount of up to $25,000,000. In September 2018, the Company drew down an additional $15,000,000 under the amended term loan agreement with CRG, no additional draw was taken. Under the terms of the amended term loan agreement, the related fixed interest rate was 10.0%, 8.0% of the interest was due and payable in cash and at the election of the Company, 2.0% of the interest due and payable may be "paid in kind". All unpaid principal, and accrued and unpaid interest, was due and payable in full on December 31, 2022.

On October 29, 2020, in connection with the consummation of the Loan and Security agreement with Stifel Bank as noted below, the Company repaid all amounts outstanding under the term loan with CRG.

Stifel Bank

In October 2020, the Company entered into a Loan and Security Agreement, or Loan Agreement, with Stifel Bank which provides 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. Any borrowings under the revolving loan facility mature on October 29, 2022, or October 29, 2023 if as of October 29, 2022, no event of default has occurred and we are in compliance with the terms of the Loan Agreement. Borrowings under the term loan facility mature on October 29, 2024. Interest under the revolving credit facility is the greater of a) 0.5% above the "Prime Rate" as published by *The Wall Street Journal* or b) 4.75%.

Also in October 2020, the Company drew down $49,000,000 under the term loan facility and used the majority of the proceeds to pay off and terminate the prior term loan agreement with CRG totaling $46,674,000, which included a prepayment premium of $305,000, a final interest payment of $365,000 and a facility fee of $2,191,000. The Company recognized a loss on debt extinguishment of $1,119,000 in connection with the early termination of the term loan agreement with CRG. The principal amount of outstanding term loans under the Loan Agreement with Stifel Bank shall be repaid in equal monthly installments beginning on November 29, 2022. Interest under the term loan facility is the greater of a) 0.75% above the "Prime Rate" as published by *The Wall Street Journal* or b) 4.75%. The term loan may not be reborrowed once repaid, but the Company may prepay the term loan at any time without premium or penalty.

The Company also concurrently 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 Agreement or $375,000 in the event the Company completes a Liquidity Event (liquidation, merger, sale of the Company or change in control). The Success Fee Agreement 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, 2021.

Obligations under the Loan Agreement are secured by substantially all of the Company's assets. Beginning on January 15, 2021, the Loan Agreement requires that the Company maintain unrestricted cash and cash equivalents with Stifel Bank or at Stifel Bank Affiliates of at least $20,000,000. In addition, for any fiscal quarter where the Company's unrestricted cash and cash equivalents maintained with Stifel Bank or at Stifel Bank Affiliates are less than $60,000,000 for any day during such fiscal quarter, the Company must comply with a minimum revenue covenant. 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 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, 2021, the aggregate outstanding principal balance under the Loan Agreement was $49,000,000 and the annual interest rate was 4.75%. As of December 31, 2021, the Company was in compliance with all applicable financial covenants. As of December 31, 2021, management does not believe that it is probable that the above events of default will be triggered within the next twelve months, therefore, the debt is classified as short or long-term on the balance sheet based on its future maturities.

Future maturities under the Stifel Bank term loan agreement as of December 31, 2021 are as follows (in thousands):

Year Ending December 31:	**Amount**
2022	$ 6,257
2023	25,749
2024	21,457
	53,463
Less: Amount representing interest	(4,463)
Less: Amount representing debt discount and debt issuance costs	(309)
Present value of minimum payments	$ 48,691

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 2024. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of five years.

In May 2021, the Company entered into a new, non-cancelable operating lease for additional office, laboratory and manufacturing space in Minnesota that expires in November 2029. The lease agreement includes a renewal provision allowing the Company to extend this lease for two additional five year terms. In connection with the lease, the Company recognized a right-of-use asset and lease liability of $3,307,000.

Operating lease costs were $1,234,000 for the year ended December 31, 2021 and $870,000 for each of the years ended December 31, 2020 and 2019. Cash paid (net of tenant improvement allowances received) for amounts included in the measurement of operating lease liabilities was $(34,000), $769,000 and $721,000 for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, the weighted average discount rate was approximately 6.50% and the weighted average remaining lease term was 5.86 years. As of December 31, 2020, the weighted average discount rate was approximately 6.50% and the weighted average remaining lease term was 3.83 years. Balance sheet information as of December 31, 2021 consists of the following (in thousands):

	December 31,	
Operating Lease:	**2021**	**2020**
Operating lease right-of-use asset in other non-current assets	$ 5,219	$ 2,798
Operating lease liability in accrued liabilities	$ 1,294	$ 850
Operating lease liability in other liabilities	5,747	2,850
Total operating lease liabilities	$ 7,041	$ 3,700

The following table summarizes the Company's operating lease maturities as of December 31, 2021 (in thousands):

Year Ending December 31:	**Amount**
2022	$ 620
2023	1,967
2024	1,764
2025	882
2026	904
Thereafter	2,769
Total lease payments	8,906
Less: imputed interest	(1,865)
Present value of lease liabilities	$ 7,041

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. As of December 31, 2021, the Company had non-cancellable purchase obligations to suppliers of $5,661,000.

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 is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability

insurance. 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, 2021.

Contingencies

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at December 31, 2021 and 2020.

8. Redeemable Convertible Preferred Stock

Upon the closing of the Company's IPO, all shares of redeemable convertible preferred stock then outstanding converted into shares of common stock. As of December 31, 2021 and 2020, the Company does not have any redeemable convertible preferred stock issued or outstanding.

Redeemable Convertible Preferred Stock Warrants

Upon the closing of the Company's IPO, all of the outstanding redeemable convertible preferred stock warrants were exercised, or net exercised based on the IPO price of $20.00 per share, into 1,945,365 shares of common stock. As of December 31, 2021 and 2020, the Company does not have any redeemable convertible preferred stock warrants outstanding.

9. Stockholders' Equity (Deficit)

Preferred Stock

At December 31, 2021, the Company’s certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At December 31, 2021, the Company’s certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 34,980,896 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, 2021, no dividends have been declared to date. Each share of common stock is entitled to one vote.

At December 31, 2021 and 2020, the Company had reserved common stock for future issuances as follows:

	December 31,	
	2021	2020
Exercise of options under stock plan	3,780,939	4,237,828
Issuance of options and restricted stock units under stock plan	2,477,212	1,790,687
Issuance of common stock under employee stock purchase plan	922,097	632,377
	7,180,248	6,660,892

Common Stock Warrants

In connection with the IPO, the common stock warrants were cash, or net exercised based on the IPO price of $20.00 per share into 5,968 shares of common stock. As of December 31, 2021 and 2020, the Company does not have any common stock warrants outstanding.

Disgorgement Proceeds

During the year ended December 31, 2021, the Company received net proceeds of $32,000 related to the disgorgement of short-swing profits under Section 16(b) of the Exchange Act. The amount was recorded as an increase to additional paid-in capital on the balance sheet.

10. Stock Option Plans

In 2007, the Company established its 2007 Stock Option Plan which provided for the granting of stock options to employees, directors and consultants of the Company. In connection with its acquisition of NeuroCo in December 2018, the Company also assumed NeuroCo's 2015 Equity Incentive Plan. In March 2019, the Company's Board of Directors approved the termination of the 2007 Stock Option Plan and the NeuroCo 2015 Equity Incentive Plan and the adoption of the 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the Company's IPO. The 2019 Plan provides for the grant of ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were initially reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan will also include shares reserved but not issued under the 2007 Stock Option Plan, plus any share awards granted under the 2007 Stock Option Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan will also include an annual increase on the first day of each fiscal year, 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, 2021, the Company has reserved 5,016,420 shares of common stock for issuance under the 2019 Plan.

A summary of the shares available for issuance under the 2007 Stock Option Plan, NeuroCo 2015 Equity Incentive Plan and 2019 Plan, or the Plans, is as follows:

	Number of Shares
Balances, December 31, 2018	57,889
Authorized	2,317,000
Granted	(848,023)
Canceled	27,824
Balances, December 31, 2019	1,554,690
Authorized	1,250,210
Granted/Awarded	(1,079,883)
Cancelled	65,670
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

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

Stock option activity under the Company's Plans 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, 2018	4,364,377	$ 3.79	7.36	$ 33,132
Options granted	848,023	$ 22.77		

Options exercised	(873,786)	$	1.77		
Options cancelled	(27,824)	$	8.71		
Balances, December 31, 2019	4,310,790	$	7.91	7.27	$ 140,234
Options granted	1,010,843	$	40.67		
Options exercised	(1,018,779)	$	3.42		
Options cancelled	(65,026)	$	23.32		
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
Vested and exercisable at December 31, 2021	2,732,674	$	13.64	6.13	$ 81,395
Vested and expected to vest at December 31, 2021	3,780,939	$	20.45	6.71	$ 91,900

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was $29,355,000, $47,861,000 and $24,867,000, 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, 2021, 2020 and 2019 was $23.83, $18.22 and $10.17 per share, respectively. The total fair value of options vested during the years ended December 31, 2021, 2020 and 2019 was $9,076,000, $5,138,000 and $2,221,000, respectively, based on the grant date fair value.

The following table summarizes information about stock options outstanding and vested as of December 31, 2021:

	Options Outstanding			Options Vested	
Exercise Price	**Options Outstanding**	**Weighted Average Remaining Contractual Term (in Years)**	**Weighted Average Exercise Price**	**Number Exercisable**	**Weighted Average Exercise Price**
$1.35 - $3.16	868,256	4.58	$ 2.05	868,256	$ 2.05
$4.73 - $7.10	577,759	6.17	$ 5.74	542,305	$ 5.71
$8.27 - $12.41	490,391	6.06	$ 11.74	470,037	$ 11.83
$20.00 - $30.00	616,871	7.26	$ 20.00	400,815	$ 20.00
$30.93 - $46.40	682,913	8.12	$ 33.60	308,065	$ 34.34
$47.20 - $70.80	544,749	8.86	$ 57.22	143,196	$ 57.48
	3,780,939	6.71	$ 20.45	2,732,674	$ 13.64

Restricted Stock Units

In March 2020, the Company began granting restricted stock units, or RSUs, under the 2019 Plan. RSUs generally vest over four years in annual equal increments. The total grant date fair value of awards granted during the year ended December 31, 2021 and 2020 was $28,110,000 and $3,186,000, respectively. The total fair value of awards vested during the year ended December 31, 2021 was $1,893,000. No awards vested during the year ended December 31, 2020. The fair value of RSUs is based on the Company's closing stock price on the date of grant. A summary of RSUs activity for the years ended December 31, 2021 and 2020 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Balances, December 31, 2019	—	$ —
Restricted stock granted	69,040	$ 46.14
Restricted stock vested	—	$ —
Restricted stock forfeited	(644)	$ 44.62
Balances, December 31, 2020	68,396	$ 46.16
Restricted stock granted	524,023	$ 53.64
Restricted stock vested	(34,964)	$ 49.95
Restricted stock forfeited	(27,181)	$ 51.99
Balances, December 31, 2021	530,274	$ 53.01
Expected to vest at December 31, 2021	530,274	$ 53.01

2019 Employee Stock Purchase Plan

In March 2019, the Company's Board of Directors adopted the 2019 Employee Stock Purchase Plan, or the 2019 ESPP, under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total of 434,000 shares of common stock 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. As of December 31, 2021, the Company has reserved 1,089,048 shares of common stock for issuance under the 2019 ESPP. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2019 ESPP was effective upon adoption by the Company's Board of Directors but was not in use until the completion of the Company's IPO in April 2019. The 2019 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended.

As of December 31, 2021, 166,951 shares of common stock have been issued to employees participating in the 2019 ESPP and 922,097 shares were available for future issuance under the 2019 ESPP.

Stock-Based Compensation

The Company estimated the fair value of stock options using the Black–Scholes option pricing model. The fair value of employee and nonemployee stock options is being amortized on a straight–line basis over the requisite service period of the awards. The fair value of employee and nonemployee stock options was estimated using the following assumptions for the years ended December 31, 2021, 2020 and 2019:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.25 - 6.25	5.00 - 6.25	5.00 - 6.25
Expected volatility	45.0% - 50.4%	43.0% - 50.3%	42.4% - 42.9%
Risk-free interest rate	0.41% - 1.08%	0.32% - 1.41%	1.47% - 2.54%
Dividend yield	—%	—%	—%

Prior to completion of the Company's IPO in April 2019, the fair value of common stock was determined by the Company's Board of Directors, who considered, among other things, contemporaneous valuations of the Company's common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. For stock options granted after the completion of the IPO, the fair value of the underlying common stock is based on the closing price of the Company's common stock on The NASDAQ Global 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.

The fair value of the shares to be issued under the Company's 2019 ESPP was estimated using the Black-Scholes valuation model with the following assumptions for the years ended December 31, 2021, 2020 and 2019:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.50	0.50	0.50 - 0.63
Expected volatility	46.9% - 51.6%	44.4% - 76.4%	44.4% - 47.8%
Risk-free interest rate	0.03% - 0.10%	0.10% - 1.58%	1.58% - 2.45%
Dividend yield	—%	—%	—%

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

	Year Ended December 31,		
	2021	2020	2019
Cost of goods sold	$ 635	$ 339	$ 179
Research and development expenses	2,909	1,110	426
Selling, general and administrative expenses	11,068	5,777	2,372
	$ 14,612	$ 7,226	$ 2,977

As of December 31, 2021, there was total unrecognized compensation costs of $16,737,000 related to stock options expected to be recognized over a period of approximately 2.37 years, a total of $24,183,000 of unrecognized compensation costs related to unvested RSUs expected to be recognized over a period of approximately 3.32 years and $365,000 related to the ESPP, which the Company will recognize over 0.38 years.

11. Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
United States	$ (49,811)	$ (47,365)	$ (52,415)
International	—	—	—
	$ (49,811)	$ (47,365)	$ (52,415)

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,		
	2021	2020	2019
Tax at federal statutory rate	$ (10,460)	$ (9,947)	$ (11,007)
State taxes, net of federal benefit	(1,852)	(1,958)	(2,270)
Permanent differences	(5,224)	(8,489)	(4,731)
Loss on Series C warrant liability	—	—	5,330
Change in valuation allowance	17,918	22,164	12,797
General business credits	(852)	(1,268)	(319)
Other	490	(491)	208
Provision for income taxes	$ 20	$ 11	$ 8

The Company's provision for income taxes amounts 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, 2021 and 2020 consist of the following (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 77,616	$ 63,069
Research and development credits	7,732	7,191
Capitalized start-up costs/Intangibles	4	8
Accruals and reserves	2,301	2,337
Stock-based compensation	4,392	1,859
Operating lease liability	1,751	935
Interest limitation	1,314	813
Total deferred tax assets	95,110	76,212
Less: Valuation allowance	(93,207)	(75,289)
Deferred tax liabilities:		
Operating lease asset	(1,297)	(707)
Property and equipment	(606)	(216)
Total deferred tax liabilities	(1,903)	(923)
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 $17,918,000 during the year ended December 31, 2021 and increased by $22,163,000 during the year ended December 31, 2020.

As of December 31, 2021, the Company had net operating loss carryforwards of approximately $301,306,000 and $254,476,000 for federal and state income tax purposes, respectively. The federal and state net operating loss carryforwards begin to expire in 2027 and 2028, 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.

At December 31, 2021, the Company had $7,358,000 and $4,303,000 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, 2021, the Company had $3,314,000 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 would increase or decrease within twelve months of the year ended December 31, 2021. 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, 2021, 2020 and 2019.

A reconciliation of the unrecognized tax benefits from January 1, 2019 to December 31, 2021 is as follows (in thousands)

	December 31,		
	2021	2020	2019
Balance at the beginning of year	$ 2,019	$ 1,436	$ 1,348
Increases related to current years' tax positions	704	342	88
Increases related to prior years' tax positions	591	241	—
Balance at end of year	$ 3,314	$ 2,019	$ 1,436

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.

12. 401(k) Plan

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code ("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. Through December 31, 2019, the Company has made no contributions to the 401(k) plan. 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. The Company's matching contributions were $1,313,000 and $959,000 for the years ended December 31, 2021 and 2020, respectively.

13. Subsequent Events

2019 Equity Incentive Plan

In January 2022, the number of shares of common stock authorized for issuance under the 2019 Plan was automatically increased by 1,399,235 shares, which was ratified by the Company's Board of Directors in February 2022.

In January and February 2022, the Company approved the award of 21,357 RSU's under the 2019 Plan.

2019 Employee Stock Purchase Plan

In January 2022, the number of shares of common stock authorized for issuance under the 2019 ESPP was automatically increased by 349,808 shares, which was ratified by the Company's Board of Directors in February 2022.

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, 2021. 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, 2021, 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, 2021 based on the framework in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2021.

The effectiveness of the Company’s internal control over financial reporting as of December 31, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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, 2021 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

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

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 registration statement 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 doubtful accounts receivable for the years ended December 31, 2021, 2020 and 2019 (in thousands):

Description	Balance at Beginning of Year	Charged to expenses	Write offs	Balance at End of Year
Allowance for doubtful accounts receivable:				
Year ended December 31, 2021	$ 13	$ 6	$ 13	$ 6
Year ended December 31, 2020	$ 45	$ (32)	$ —	$ 13
Year ended December 31, 2019	$ 22	$ 23	$ —	$ 45

(c) Exhibits.

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form 10-K, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the registrant	8-K	001-38847	3.1	4/8/2019	
3.2	Amended and Restated Bylaws of the registrant	8-K	001-38847	3.2	4/8/2019	
4.1	Specimen Common Stock Certificate of the registrant	S-1	333-233044	4.1	8/6/2019	
4.2	Amended and Restated Registration Rights Agreement by and among the registrant and certain stockholders, dated July 7, 2017	S-1	333-233044	4.2	8/6/2019	
4.3	Amended and Restated Stockholders Agreement by and among the registrant and certain stockholders, dated July 7, 2017	S-1	333-233044	4.3	8/6/2019	
4.4	Amendment to the Amended and Restated Registration Rights Agreement, dated March 21, 2019	S-1	333-233044	4.4	8/6/2019	
4.5	Description of the registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934					*
10.1	Form of Indemnification Agreement for directors and executive officers	S-1	333-233044	10.1	8/6/2019	
10.2+	2007 Stock Plan, as amended, and related form agreement	S-1	333-233044	10.2	8/6/2019	
10.3+	2019 Employee Stock Purchase Plan and related form agreements	S-1	333-233044	10.3	8/6/2019	
10.4+	Executive Incentive Compensation Plan	S-1	333-233044	10.4	8/6/2019	
10.5+	2019 Equity Incentive Plan and related form agreements	S-1	333-233044	10.5	8/6/2019	
10.6#	Supply Agreement by and between the registrant and Cordis Corporation, dated October 21, 2011, as amended by the Amendment dated March 12, 2012, the Second Amendment to Supply Agreement dated July 12, 2012, the Third Amendment to Supply Agreement dated April 19, 2013 and the Fourth Amendment to Supply Agreement dated April 9, 2018	S-1	333-233044	10.6	8/6/2019	
10.7#	License Agreement by and between the registrant and Cordis Corporation, dated December 17, 2010	S-1	333-233044	10.7	8/6/2019	
10.8	Quality Assurance Agreement by and among the registrant and Lake Region Medical and affiliates, dated May 4, 2015	S-1	333-233044	10.8	8/6/2019	
10.9#	Amended and Restated Manufacturing and Supply Agreement by and between the registrant and Galt Medical Corporation, dated January 10, 2018	S-1	333-233044	10.9	8/6/2019	
10.1	Term Loan Agreement by and among the registrant, certain affiliates of CRG Partners III L.P. as lenders and certain subsidiary guarantors, dated October 13, 2015, as amended by Amendment No. 1 to Term Loan Agreement dated January 3, 2017, Amendment No. 2 to Term Loan Agreement dated June 22, 2017, Amendment No. 3 to Term Loan Agreement dated November 30, 2017, Amendment No. 4 to Term Loan Agreement dated June 25, 2018, Amendment No. 5 to Term Loan Agreement dated September 4, 2018, Amendment No. 6 to Term Loan Agreement dated November 14, 2018 and effective as of October 31, 2018, and Amendment No. 7 to Term Loan Agreement dated June 11, 2019	S-1	333-233044	10.1	8/6/2019	
10.11	Lease Agreement by and between the registrant and Hanover Properties Ltd., dated November 30, 2017	S-1	333-233044	10.11	8/6/2019	
10.12	Director Offer Letter for Donald Zurbay dated as of February 6, 2018	S-1	333-233044	10.12	8/6/2019	
10.13+	Confirmatory Employment Letter between the registrant and Erica Rogers, dated as of March 21, 2019	S-1	333-233044	10.13	8/6/2019	
10.14+	Confirmatory Employment Letter between the registrant and Lucas Buchanan, dated as of March 21, 2019	S-1	333-233044	10.14	8/6/2019	
10.15+	Confirmatory Employment Letter between the registrant and Richard Ruedy, dated as of March 21, 2019	S-1	333-233044	10.15	8/6/2019	
10.16+	Confirmatory Employment Letter between the registrant and Andrew Davis, dated as of March 21, 2019	S-1	333-233044	10.16	8/6/2019	
10.17+	Change in Control and Severance Agreement between the registrant and Erica Rogers, dated as of March 21, 2019	S-1	333-233044	10.17	8/6/2019	
10.18+	Change in Control and Severance Agreement between the registrant and Lucas Buchanan, dated as of March 21, 2019	S-1	333-233044	10.18	8/6/2019	
10.19+	Change in Control and Severance Agreement between the registrant and Richard Ruedy, dated as of March 21, 2019	S-1	333-233044	10.19	8/6/2019	
10.20+	Change in Control and Severance Agreement between the registrant and Andrew Davis, dated as of March 21, 2019	S-1	333-233044	10.2	8/6/2019	
10.21†	Loan and Security Agreement, dated as of October 29, 2020, by and between Silk Road Medical, Inc. and Stifel Bank.	8-K/A	333-230045	10.1	11/4/2020	

10.22†	First Amendment to Loan and Security Agreement, dated January 15, 2021, by and between the registrant and Stifel Bank.	10-Q	001-38847	10.22	5/10/2021	
10.23	Lease Agreement by and between the registrant and ARHC UHPTHMN01 LLC, dated May 12, 2021.	10-Q	001-38847	10.23	8/6/2021	
23.1	Consent of Independent Registered Public Accounting Firm					*
24.1	Power of Attorney					*
31.1	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
31.2	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

* Filed herewith.

** Furnished herewith.

\+ 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.

March 1, 2022 By: /s/ Erica J. Rogers
Erica J. Rogers
President, Chief Executive Officer and Director

March 1, 2022 By: /s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Financial Officer and Chief Operating Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Erica J. Rogers and Lucas W. Buchanan, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, with full power of each to act alone, with full powers of substitution and resubstitution, for him and in his 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 he 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/ Erica J. Rogers Erica J. Rogers	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2022
/s/ Lucas W. Buchanan Lucas W. Buchanan	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2022
/s/ Rick D. Anderson Rick D. Anderson	Director	March 1, 2022
/s/ Kevin J. Ballinger Kevin J. Ballinger	Director	March 1, 2022
/s/ Tanisha V. Carino Tanisha V. Carino	Director	March 1, 2022
/s/ Tony M. Chou Tony M. Chou, M.D.	Director	March 1, 2022
/s/ Jack W. Lasersohn Jack W. Lasersohn	Chair of the Board of Directors	March 1, 2022
/s/ Elizabeth H. Weatherman Elizabeth H. Weatherman	Director	March 1, 2022
/s/ Donald J. Zurbay Donald J. Zurbay	Director	March 1, 2022