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, 2019 .

OR

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

For the transition period from to

Commission File Number: 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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 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 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 $818.0 million as of February 28, 2020 based on the closing sale price of the registrant's common stock on

the NASDAQ Global 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, 2020, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 31,353,906.

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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 expected uses of the net proceeds from our initial public offering;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;

- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our ability to identify and develop new and planned products and/or acquire new products; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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 surgical procedures for 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 for use in patients who require carotid revascularization, but are at high risk for adverse events from carotid endarterectomy and who meet certain treatment criteria. As of December 31, 2019, more than 16,000 TCAR procedures have been performed globally, including more than 8,400 in the United States in 2019.

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 2018, with an estimated 427,000 new diagnoses in 2018, 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 83% of the approximately 168,000 carotid revascularization

procedures performed in the United States in 2018. 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 427,000 new carotid artery disease diagnoses that occurred in the United States in 2018, we believe a total annual U.S. market opportunity of approximately $2.6 billion exists for our portfolio of TCAR products. There were approximately 168,000 carotid revascularization procedures performed in 2018, which we estimate to represent a market conversion opportunity greater than $1.0 billion. More than 8,400 TCAR procedures were performed in 2019 in the United States using our products, representing less than 2% of annual diagnoses of carotid artery disease in the United States.

The safety, effectiveness and clinical advantages of TCAR have been demonstrated in multiple clinical trials, post-market studies and registries that have evaluated outcomes in more than 11,900 patients or patient pairs in propensity matched scoring analysis in the United States and Europe 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%. Additionally, data on real-world outcomes of TCAR relative to CEA and CAS have continued to accrue through the ongoing TCAR Surveillance Project, which is an ongoing open-ended registry sponsored by the Society for Vascular Surgery through the Vascular Quality Initiative, or VQI. In June 2019, updated outcomes from the TCAR Surveillance Project were presented at the 2019 Vascular Annual Meeting, or VAM. In a propensity matched analysis of TCAR and CEA with 5,160 patients in each cohort, TCAR provided similar in-hospital stroke rates as compared to CEA but had significantly lower odds of in-hospital myocardial infarction and 30-day death and composite stroke and death, and TCAR patients were less likely to suffer a cranial nerve injury and remain in the hospital longer than one day. In a study published in the *Journal of the American Medical Association* in December 2019, a propensity matched analysis of 3,286 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.

We manufacture the ENROUTE NPS and distribute our portfolio of TCAR products from our facility in Sunnyvale, California. We market and sell our products in the United States through a direct sales organization consisting of 35 sales representatives and 61 clinical support specialists as of December 31, 2019, 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 over 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, and we estimate that the high surgical risk patient population represents approximately two-thirds of the treated patient population. We plan to pursue expansion of FDA labeling for the ENROUTE stent, currently indicated for use in certain patients at high risk for adverse events from CEA, and, upon FDA approval of broader indication(s), pursue CMS coverage for our products in the remaining one-third of treated patients who qualify under such broader indication(s), including patients who are deemed standard surgical risk.

We have experienced considerable growth since we began commercializing our products in the United States in late 2015. Our revenue increased to $63.4 million for the year ended December 31, 2019 compared to $34.6 million for the year ended December 31, 2018, representing growth of 83%, and our net losses were $52.4 million and $37.6 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, our accumulated deficit was $191.5 million and $139.1 million, respectively.

Our Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- **Paradigm-shifting transcarotid access and flow reversal technologies.** TCAR, as pioneered by our FDA-approved products, presents an entirely new, minimally-invasive procedure in a disease state where conventional surgical treatment options have not advanced significantly for over 60 years. TCAR combines two key concepts: minimally-invasive direct carotid access in the neck, and high-rate blood flow reversal to protect the brain. Our technology combines the benefits of innovative endovascular techniques with fundamental surgical principles. Our goal is to leverage our disruptive technology and growing body of clinical evidence to establish our products as the part of an improved standard of care for treating qualifying patients who require carotid revascularization.

- **Compelling body of clinical and economic evidence.** The benefits of TCAR are supported by data from over 11,900 patients enrolled across several multi-center clinical trials, post market studies and real-world registries that support favorable patient outcomes and value-based care. In November 2015, the Journal of Vascular Surgery reported that TCAR demonstrated the lowest 30-day stroke rate of any prospective, multicenter carotid stent trial. Data from the Society for Vascular Surgery's TCAR Surveillance Project show that TCAR compares favorably to CEA and CAS with a low in-hospital and 30-day stroke and death risk and low procedure-related adverse events. TCAR has demonstrated shorter procedure times, a shorter length of hospital stay and reduced adverse event rates compared to the standard of care, CEA. For hospitals seeking to improve quality metrics, drive throughput and increase profitability, we believe TCAR results in higher efficiency and increased cost savings. In addition, by reducing the overall burden of stroke, we believe TCAR is beneficial to payers. We believe our growing body of clinical evidence and favorable value proposition will continue to support increased adoption of TCAR.

- **Established reimbursement linked to our unique regulatory label.** TCAR is reimbursed under established codes and payment levels. CMS coverage for TCAR in certain high surgical risk patients treated at facilities participating in the Society for Vascular Surgery's TCAR Surveillance Project mandates the use of FDA-cleared transcarotid flow reversal neuroprotection devices and FDA-approved transcarotid stents. We are currently the only company to have obtained transcarotid FDA labeling, thereby offering the only transcarotid devices currently eligible for CMS reimbursement coverage through the Society for Vascular Surgery's TCAR Surveillance Project.

- **Procedure-focused approach to product innovation and service.** Our product portfolio was developed to support the technical aspects of TCAR and is currently the only suite of devices specifically designed for carotid access through the neck, or the transcarotid approach. Our research and development strategy strives to optimize safety, effectiveness and ease-of-use through a family of integrated products designed to minimize the learning curve and drive adoption by physicians. In addition, our commercial organization is clinically consultative and trained in many aspects of carotid artery disease treatment, from patient selection and pre-operative planning to procedural support and post-operative care. As a result, our commercial organization provides a level of service and support that we believe is valued by our physician customers and drives customer loyalty.

- **Strong relationships and engagement with key medical societies and governmental agencies.** We have developed strong working relationships with key groups including the FDA, CMS, and the Society for Vascular Surgery. By listening and responding to the needs of key stakeholders, we believe we have been able to achieve efficient regulatory approval timelines, coverage and alignment with key medical societies in the vascular field regarding the benefits of TCAR. We believe our approach to engaging these key stakeholders will continue to help drive our business success.

- **Broad intellectual property portfolio.** As of December 31, 2019 , we held 76 patents globally that include device, apparatus and method claims surrounding TCAR and our suite of current and potential future products, as well as for treating other vascular diseases and enabling other transcarotid procedures, primarily directed at acute ischemic stroke, other neurovascular procedures, repair of the aorta and transcatheter aortic valve repair, or TAVR. In addition, we believe that our trade secrets, including manufacturing know-how, provide additional barriers to entry.

- **Industry-experienced senior management team**. Our senior management team consists of seasoned medical device professionals with deep industry experience. Our team has successfully lead and managed dynamic growth phases in organizations and commercialized products in markets driven by converting open surgical procedures to endovascular alternatives and expanding access to new procedures for patients. Members of our team have worked with well-regarded medical technology companies such as Boston Scientific, Medtronic, Abbott, Johnson & Johnson, Stryker, Cardinal Health and Roche.

Our Market Opportunity

The Burden of Stroke

Stroke is a disease that affects the arteries leading to and within the brain. There are two key types of stroke: an ischemic stroke, which occurs when a blood vessel that carries oxygen and nutrients to the brain is blocked by a clot, and a hemorrhagic stroke, which occurs when one of these same blood vessels ruptures. If blood flow is stopped for more than a few seconds, the brain is deprived of oxygenated blood and brain cells can die. Depending on where in the brain the stroke occurs, the consequences of stroke can include difficulty talking, memory loss, cognitive issues, paralysis or loss of muscle movement, inability to attend to bodily needs or care, pain, emotional problems, and death.

Although stroke is often considered preventable, it remains one of the most catastrophic and common conditions worldwide. The American Heart Association, or AHA, estimated that the global prevalence of stroke was 42.4 million in 2015, with ischemic strokes representing approximately 87% of the total number of strokes in the U.S. and approximately two thirds of all strokes worldwide. According to a 2013 study published in the Neuroepidemiology Journal, there are an estimated 6.9 million new or recurrent ischemic strokes globally each year. The AHA expects the incidence of stroke to more than double between 2010 and 2050 as demographic trends contribute to an increase in the prevalence of disease states that are commonly associated with strokes.

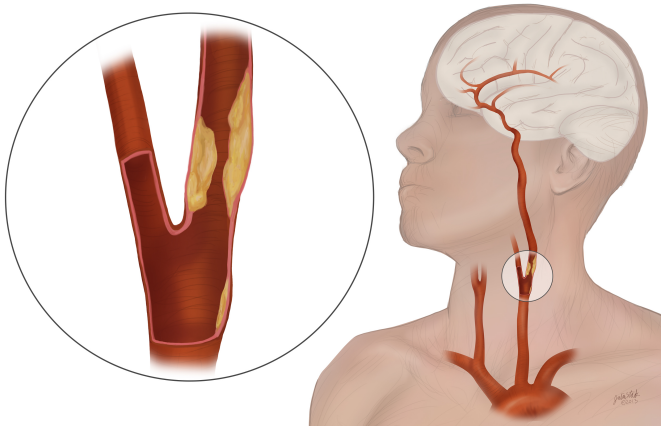
In the United States, stroke is a major contributor to long-term disability and mortality and disproportionately affects women, the elderly and certain ethnic populations. According to the AHA, stroke was the fifth leading cause of death in the United States in 2014, and results in the death of approximately 140,000 people each year. Stroke ranked in the top 10 most expensive conditions for Medicare, Medicaid, and private insurers in 2013, and according to the AHA, direct medical stroke-related costs will more than double in the United States, from $36.7 billion in 2015 to $94.3 billion in 2035.

We believe the best way to mitigate the mortality, morbidity and cost burden of stroke is to prevent strokes in the first place. While strokes can be caused by a wide variety of conditions, the Society for Vascular Surgery estimates that carotid artery disease is the primary cause of up to one-third of strokes. Based on AHA's estimated 690,000 ischemic strokes in the United States every year, carotid artery disease is the cause of up to 230,000 ischemic strokes annually. Clinical evidence has demonstrated that with proper diagnosis and treatment, stroke due to carotid artery disease is mostly preventable.

Overview of Carotid Artery Disease

Carotid artery disease, also known as carotid artery stenosis, is the narrowing of the carotid arteries that reside in the neck, one on each side, which are two of the four main blood vessels that supply oxygen to the brain. The narrowing of the carotid arteries is usually caused by atherosclerosis, which is the buildup of cholesterol, fat, calcium and other substances on the walls of arteries. Over time and as people age, an area of atherosclerotic plaque, also called a lesion, is formed. Plaque buildup can lead to narrowing or blockage in the carotid artery, often at the bifurcation of the common carotid and internal carotid arteries.

Carotid plaques in particular are often unstable or crumbly, and a piece of plaque or a blood clot, known as emboli, can break away from the wall of the carotid artery, travel through the bloodstream and get stuck in one of the brain's smaller arteries. When these arteries experience an interrupted or seriously reduced blood supply, the surrounding cells and tissue are deprived of oxygen leading to an ischemic stroke.



Diagnosis and Referral Pathways for Carotid Artery Disease

Based on data from Modus Health Group, carotid artery disease was prevalent in approximately 4.3 million people in the United States in 2018, which represented approximately 1.7% of the adult population in 2018, and reflects an increase in prevalence from approximately 4.1 million people in the

United States in 2017. Prevalence generally increases with age. Unfortunately for many patients, carotid artery disease is frequently asymptomatic, or silent, and the first symptom is often a stroke. In 2018, an estimated 427,000 patients in the United States were diagnosed with carotid artery disease severe enough to warrant treatment, reflecting an increase from an estimated 403,000 patients in 2017. Patients are diagnosed with carotid artery disease either because they have been non-invasively screened for the disease or they have experienced symptoms ranging from a major or minor stroke to a transient ischemic attack, or TIA, in which neurologic symptoms resolve within 24 hours.

For asymptomatic patients, a primary care physician or a specialist such as a vascular surgeon or cardiologist may screen for carotid artery disease based on the presence of risk factors, including age, family history, history of smoking, high cholesterol, high blood pressure, obesity, diabetes or atherosclerosis in other areas like the heart and legs. When a potential carotid stenosis is detected, the physician will typically refer the patient to a vascular laboratory for a non-invasive ultrasound to definitively diagnose the presence and degree of stenosis, or narrowing of the artery. The degree of stenosis is reported as a percentage of the vessel diameter. There is a correlation between higher degrees of stenosis and increased risk of stroke.

Symptomatic patients who have survived a stroke or experienced a TIA are typically referred to a neurologist for care and physiological assessment. If the patient is found to have underlying carotid artery stenosis, the neurologist will typically refer the patient to a vascular surgeon for urgent treatment to prevent a recurrent stroke. The majority of patients in the United States who are referred for a carotid revascularization procedure receive care from a vascular surgeon.

Once a patient is diagnosed with carotid artery disease, the treatment paradigm is influenced by the patient's symptom status, disease progression and degree of stenosis, as well as factors that may place them at higher risk of adverse events, including their age, anatomic characteristics, and co-morbidities such as cardiovascular and respiratory disease. Patients diagnosed with carotid artery disease are recommended for treatment with medical management, which includes pharmaceutical treatments and lifestyle modifications such as smoking cessation and control of diabetes, hypertension and lipid, or fatty acid, abnormalities. As the degree of stenosis increases, carotid revascularization procedures may also be prescribed.

For example, published guidelines by the Society for Vascular Surgery recommend that symptomatic patients be treated with CEA if they present with carotid artery stenosis greater than or equal to 50%. For asymptomatic patients, the guidelines recommend CEA for stenosis greater than or equal to 60%, provided that the risk of stroke and death within 30 days of the procedure is below 3% and life expectancy is greater than three years. The risk of stroke and death within 30 days is subjective and typically depends on the patient's surgical risk factors as well as the skill and experience of the treating physician. The guidelines for CAS procedures are more limiting than those for CEA procedures due primarily to the increased stroke risk associated with CAS.

In 2018, of the estimated 4.3 million individuals in the United States with carotid artery disease, and of the approximately 427,000 patients that were newly diagnosed, approximately 168,000 patients were treated with a revascularization procedure, representing an increase of approximately 6% in newly diagnosed patients relative to 403,000 patients in 2017, and an increase of approximately 10% in revascularization procedures relative to approximately 152,000 procedures in 2017. The remaining patients are managed medically and monitored to assess the progression of stenosis and any new or recurrent neurologic symptoms.

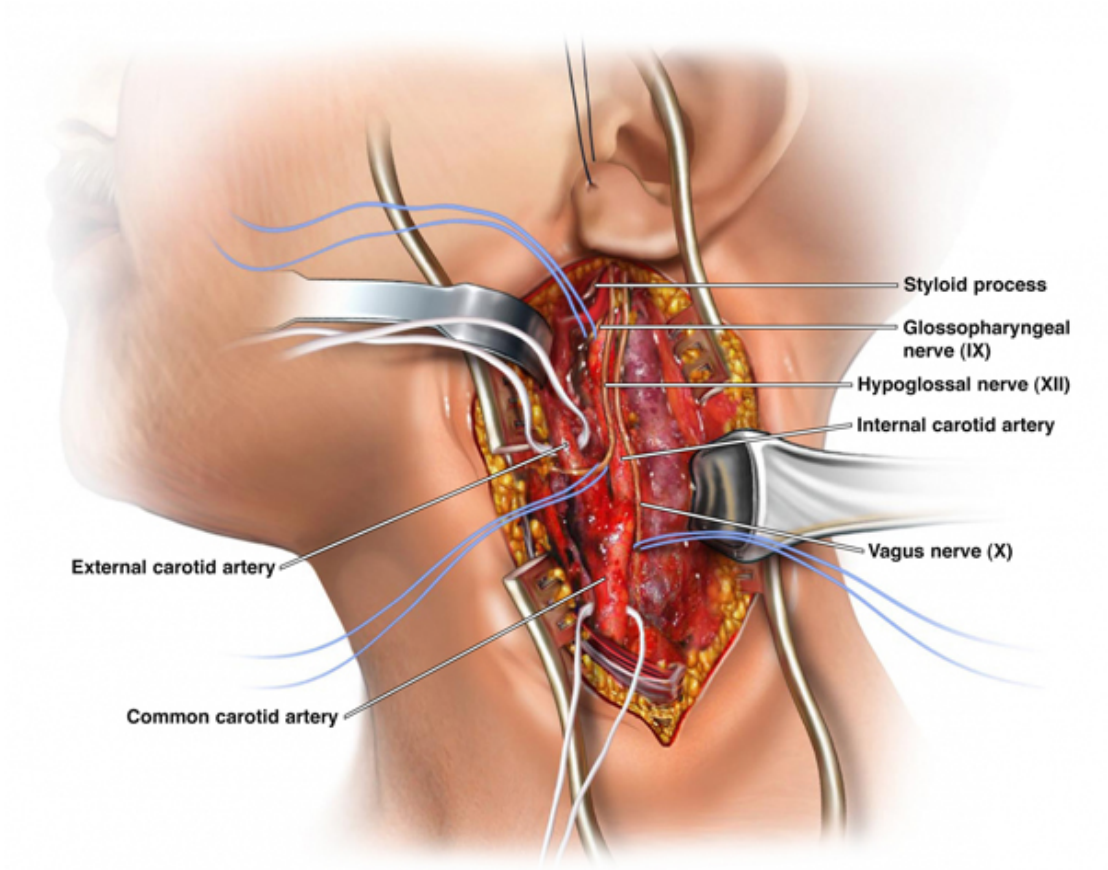
Existing Alternatives for Carotid Revascularization and Their Limitations

Existing treatment options for carotid revascularization procedures include CEA and CAS. Both surgical removal of plaque with CEA and stenting of plaque with CAS have demonstrated clinical effectiveness in reducing long-term stroke risk, which is stroke occurring more than 30 days after the procedure. This has been shown in multiple randomized trials across different surgical techniques and

stent designs, including trials with multi-year follow up that, in some cases, extend out to 10 years. However, CEA and CAS have been associated with adverse events within 30 days.

Carotid Endarterectomy, or CEA

CEA, which was first performed in 1953, is an invasive surgical procedure, typically performed under general anesthesia. The procedure involves a ten- to fifteen-centimeter incision extending from the base of the neck towards the earlobe, followed by the meticulous dissection of multiple tissue and muscle layers to open and expose the internal, external and common carotid arteries, collectively known as the carotid bifurcation. During the surgical exposure of the carotid bifurcation, great care is required to avoid damaging the cranial nerves that travel in and around the carotid arteries and related veins. Damage to these nerves, which control functions like speaking, swallowing, facial sensation, taste and saliva production, is a potential side-effect of CEA and can result in transient and permanent quality of life issues and stroke-like symptoms.



Once the bifurcation is exposed, the carotid arteries are then clamped above and below the disease, temporarily halting blood flow to the brain from that artery, so that the artery can be cut open to remove the plaque. Due to the length of the surgery, a shunt is sometimes placed to allow blood flow to bypass the clamped arteries and reach the brain. After the plaque is removed, the artery is closed, and the vessels are unclamped to restore blood flow. The long incisional wound is then sutured closed, though the resulting scar presents a cosmetic disadvantage.

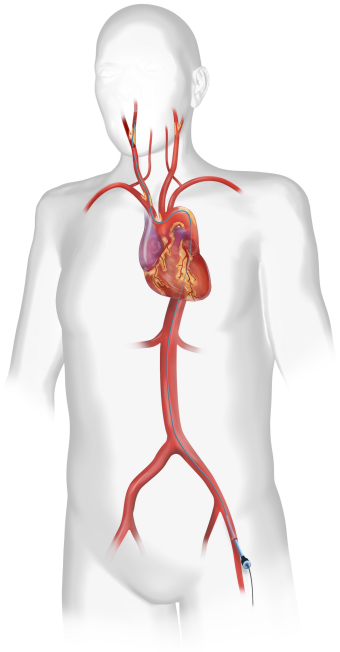
Data from large randomized clinical trials have demonstrated that CEA in addition to medical management is more effective at reducing long-term stroke risk than medical management alone, which has established CEA as the standard of care. Importantly, many of these trials primarily included standard surgical risk patients who were relatively young, free of co-morbidities and deemed reasonably able to withstand the stress of an invasive surgery.

Data from these trials and other studies, including real world registries, have indicated that the surgical impact from a large incision combined with factors such as procedure time, general anesthesia and patient-specific risk factors can result in known adverse events, including nerve injury, heart attack and even stroke and death. CEA also presents a risk of wound complications, including bleeding and infection, and leaves behind a significant scar. These adverse events can also lead to longer hospital stays that are costly to providers and payers. Further, patient recovery times can be significant after a major vascular surgery like CEA.

Transfemoral Carotid Artery Stenting, or CAS

To address the invasiveness of CEA, in the 1990s physicians and medical device companies developed CAS, which uses minimally-invasive techniques to place a stent in the carotid artery. The first carotid stents were approved by the FDA in 2004 for high surgical risk patients, marking the beginning of the CAS market in the United States.

In a CAS procedure, a small puncture is made in the groin and a sheath is inserted through which a physician can navigate catheters. The physician navigates the catheters inside the body through approximately three feet of vessels and arteries of the leg, abdomen, chest and neck, up to and often beyond the lesion itself, in order to place a stent to brace the plaque and prevent it from embolizing. Significant technical skill is required to maneuver catheters through these vessels and their twists and turns. Patients may also have significant atherosclerotic disease along the navigation pathway, and the catheters can scrape the inner lining of the arteries and dislodge plaque and embolic debris, which can travel to the brain and cause neurologic injury or stroke during or after the procedure. While embolic protection devices, which are designed to capture debris dislodged during the procedure, may be used to reduce these risks, the brain is not protected while they are maneuvered into place, and they do not always safely capture all debris once in position.



While CAS is less invasive than CEA, multiple randomized clinical studies and real-world registries have consistently shown an almost two-fold increase in the risk of stroke within 30 days relative to CEA. CAS has also been clinically demonstrated to result in showers of microemboli to the brain, which can cause neurologic injuries including memory loss as well as cognitive decline and dementia while increasing the risk of future stroke. The procedure-related stroke risks are further elevated in elderly, female, symptomatic and other at-risk patients who tend to have smaller or more distended and diseased vessels. As a result, CAS is performed in a minority of carotid revascularization procedures, representing only 14% of the estimated 168,000 carotid procedures performed in the United States in 2018. By contrast, after multiple decades of technology innovation and clinical development, minimally-invasive endovascular procedures targeted at arterial diseases in the legs, abdomen, heart and brain have become the standard of care and represented approximately 70% to 85% of procedures in other areas of the vasculature in 2012 as compared to open surgical alternatives.

Major Trials Comparing CEA and CAS

The principal clinical trial evaluating CEA and CAS is the Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis trial, known as CREST. CREST was a multi-center randomized controlled trial in the United States that compared CEA to CAS in symptomatic and asymptomatic patients deemed to be at standard risk for adverse events from CEA, or standard surgical risk. This trial, which by protocol excluded high surgical risk patients, was sponsored by the National Institutes of Health and is considered by many physicians to be the landmark trial comparing CEA and CAS. A number of other randomized controlled trials have further established the basis of comparison between CEA and CAS. In addition, post-market registries sponsored by the Society for Vascular Surgery have assessed CEA and CAS in real world practice. Results comparing CEA and CAS from the CREST trial and the Society for Vascular Surgery registry are shown in tables below. In our presentation of the results of the CREST trial, we have indicated incidence rates in percentage terms, regardless of sample size. Statistically significant differences are demonstrated by p-values of less than 0.05, which is the commonly accepted threshold for statistical significance. This follows the convention of standard clinical practice.

CREST Trial Results

Patient Cohort			30-day Stroke Incidence	30-day Stroke p-value	30-day Stroke/Death Incidence	30-day Stroke/Death p-value	4 Year Ipsilateral Stroke Incidence	4 Year Ipsilateral Stroke p-value
All Patients	CEA	n=1,240	2.3%	0.01	2.3%	0.005	1.7%	NR
	CAS	n=1,262	4.1%		4.4%		1.6%	
Asymptomatic	CEA	n=587	1.4%	0.15	1.4%	0.15	0.9%	NR
	CAS	n=594	2.5%		2.5%		1.5%	
Symptomatic	CEA	n=653	3.2%	0.043	3.2%	0.019	2.5%	NR
	CAS	n=668	5.5%		6.0%		1.7%	
Male	CEA	n=823	2.4%	0.26	2.4%	0.13	1.3%	NR
	CAS	n=807	3.3%		3.7%		1.6%	
Female	CEA	n=417	2.2%	0.013	2.2%	0.013	2.4%	NR
	CAS	n=455	5.5%		5.5%		1.5%	
Age ≥75 years	CEA	n=353	3.1%	0.035	3.7%	NR	1.4%	NR
	CAS	n=333	6.9%		8.1%		3.0%	
Age <75 years	CEA	n=887	2.0%	NR	2.1%	NR	1.8%	NR
	CAS	n=929	3.1%		3.6%		1.1%	

NR - p-values not reported; rates are manually calculated from data presented in the respective publications.

While there was a statistically significant difference in 30-day stroke and 30-day stroke/death favoring CEA, CAS had a significantly lower rate of myocardial infarction of 1.1% compared to CEA at 2.3%, with a p-value equal to 0.03. We believe that this can be largely attributed to the more invasive nature of CEA.

In the FDA analysis of CREST which led to FDA approval of a carotid stent for use in standard surgical risk patients, the rate of acute cranial nerve injury was a secondary endpoint. Patients with an acute cranial nerve injury were evaluated again at the 6-month follow-up visit to determine if the injury persisted. As shown in the table below, patients randomized to the CEA arm had a statistically significant higher rate of acute cranial nerve injury, many of which persisted at the 6-month evaluation. Eighty percent of the cranial nerve injuries involved a motor deficit, such as difficulty swallowing.

Cranial Nerve Injury	CEA	CAS	p-value
	n=1,176	n=1,131	
Cranial Nerve Injury *(Acute)*	5.3%	0.0%	<0.0001
Cranial Nerve Injury *(Persisting at 6 months)*	2.1%	0.0%	<0.0001

In an analysis of patients who received their randomized treatment assignment without crossover, CEA procedure time was more than twice that of CAS. Additionally, CEA patients had a hospital length of stay of 3.0 days compared to 2.6 days for CAS patients. The difference in hospital length of stay was statistically significant.

Procedural Information	CEA	CAS	p-value
	n=1,193	n=1,213	
Mean procedure time (mins)	171	69	NR
Length of stay (days)	3.0	2.6	0.011

In a publication of the primary long-term endpoint of post-procedural ipsilateral stroke, or a stroke on the same side as the original carotid revascularization procedure, over the 10-year follow-up period, ipsilateral stroke occurred in 6.9% of CAS patients and 5.6% of CEA patients. The difference was not statistically significant. Furthermore, there was no statistical difference when outcomes were analyzed separately for symptomatic and asymptomatic patients. There was also no statistical difference between CAS and CEA at any other year of follow-up from year one through year nine. These data demonstrate that both CAS and CEA provide the same durable reduction of long-term stroke risk.

Society for Vascular Surgery Vascular Registry

In 2013, members of the Society for Vascular Surgery Vascular Registry, the precursor to the VQI, published outcomes for CEA and CAS in high surgical risk patients using CMS high risk criteria per the National Coverage Determination. The objective of the analysis was to determine objectively if the CMS high risk criteria demonstrated differential and biased outcomes in CEA and CAS due to the over-representation of high risk patients for CAS. The authors also sought to determine if the rate of adverse events in high risk patients is lower in CAS than CEA as the surgical high risk criteria would suggest. The primary endpoint was a composite of stroke, death and myocardial infarction at 30 days. In a risk adjusted analysis, CAS had a significantly higher rate of stroke, death and myocardial infarction compared to CEA. For the high risk cohort, the rates of stroke for CEA and CAS were 3.6% and 4.9%, respectively; the rates of stroke and death for CEA and CAS were 4.8% and 6.2%, respectively.

	CEA High Risk			CAS High Risk		
	Symptomatic	Asymptomatic	All	Symptomatic	Asymptomatic	All
	n=936	n=1,418	n=2,354	n=1,538	n=1,844	n=3,382
Stroke/death/myocardial infarction	7.3%	5.0%	5.9%	9.1%	5.4%	7.1%
Stroke/death	6.4%	3.7%	4.8%	7.9%	4.8%	6.2%
Stroke	4.9%	2.7%	3.6%	6.7%	3.4%	4.9%

Our Solution

With our portfolio of TCAR products, we have pioneered a new approach for the treatment of patients who are at high risk for adverse events from CEA and qualify for a TCAR procedure, and we are seeking to expand the indication for our TCAR products in an effort to improve the standard of care for treating carotid artery diseases or conditions that require carotid revascularization. TCAR is a minimally-invasive solution that addresses the risk of morbidity of CEA and the 30-day stroke risk of CAS, while providing the equivalent clinical benefit of these conventional surgical procedures and a reduction in long-term stroke risk. We believe that by meeting the standard of brain protection and reduction in 30-day and long-term stroke risks associated with CEA in a minimally-invasive manner, TCAR offers an attractive alternative for patients, providers and payers and has the potential to successfully penetrate the entire carotid revascularization market. We plan to seek FDA approval for expanded indication(s) to make our TCAR products and related procedures available to more patients who may benefit from such surgical procedures.

Transcarotid Artery Revascularization, or TCAR

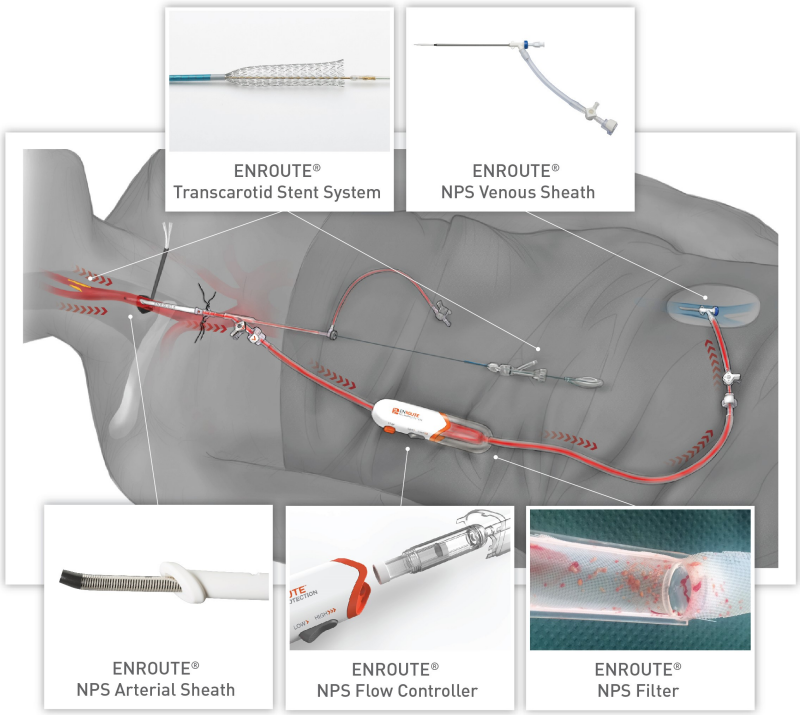
TCAR relies on two novel concepts: minimally-invasive direct carotid access in the neck, and high-rate blood flow reversal during the procedure to protect the brain.

The TCAR procedure begins with a two- to three-centimeter incision slightly above the collarbone, thereby obviating the need to maneuver catheters from the groin. The incision is made just above the collarbone to expose a small section of the carotid artery well below the carotid stenosis and most of the cranial nerves. A puncture is made into the carotid artery using our transcarotid access kit, and our

proprietary sheath is placed inside the carotid artery. This sheath is connected to the rest of our flow reversal system, which lies outside the body, and ends in a connection to our venous sheath in the patient's groin. After the carotid artery is clamped just below the sheath, the pressure gradient between the high-pressure arterial system in the neck and the low-pressure venous system in the groin creates the blood flow reversal, which redirects dislodged plaque and debris away from the brain where it is captured in an external filter in our system.

While the brain is protected by flow reversal, our guidewire is navigated across the lesion and our transcarotid stent is delivered and placed in the carotid artery to stabilize the plaque against the wall of the artery, trapping the lesion and reducing the risk of a future stroke. The short distance enabled by our transcarotid access allows for accurate stent placement. Balloon catheters can also be used to pre-dilate the lesion or further expand the stent when appropriate. Any debris released during these steps of the procedure is directed safely away from the brain by the flow reversal. Clinical studies have shown that patients can tolerate this temporary redirection of blood flow, which usually lasts for approximately ten minutes, due to the redundant network of arteries in the brain that enable it to receive blood flow and oxygen through multiple pathways. After our transcarotid stent is implanted, the blood flow is returned to normal, the system is removed, and the artery and small wound are sutured closed.

The following diagram depicts our portfolio of TCAR products:



Key Clinical Advantages of TCAR

We believe the key advantages of TCAR relative to CEA and CAS include:

- ***Reduction in stroke risk.*** In our pivotal ROADSTER clinical trial, TCAR demonstrated a 30-day stroke rate of 1.4% in 141 high surgical risk patients. In the study publication from the Journal of Vascular Surgery in November 2015, the authors reported that the 30-day stroke rate of 1.4% was the lowest reported for any prospective, multicenter trial of carotid artery stenting. Our ROADSTER 2 post approval study was completed in 2019 and showed a 30-day stroke rate of 0.6% in 632 patients. In separate propensity matched analyses from the TCAR Surveillance Project, TCAR showed similarly low in-hospital strokes rates compared to CEA (odds ratio 0.80; 95%CI 0.58-1.11; p=0.19) and statistically significant lower in-hospital stroke rates compared to CAS (1.3% for TCAR versus 2.4% for CAS; Relative Risk 0.54 95%CI 0.38 to 0.79; p=0.001).

- ***Low surgical morbidity***. The minimally-invasive nature of TCAR offers inherent advantages that can mitigate adverse events typically associated with CEA, including cranial nerve injury and myocardial infarction. Propensity matched data from the Society for Vascular Surgery's TCAR Surveillance Project in 5,160 patients in each cohort showed TCAR provided a statistically significant reduction in the rate of in-hospital cranial nerve injury, myocardial infarction and composite stroke, death and myocardial infarction as compared to CEA patients. Similarly, data from our ROADSTER study indicated that TCAR had a heart attack rate of 0.7% in high surgical risk patients within 30 days of the procedure. CREST data regarding standard surgical risk patients showed a 30-day heart attack rate of 2.3% and 1.1% for CEA and CAS, respectively.

- ***Minimal patient discomfort and rapid recovery.*** While the typical incision required for CEA is ten to fifteen centimeters long, the TCAR incision is generally two to three centimeters long, leaving behind a much smaller wound and scar that often only requires non-opioid pain medications and little more than a steri-strip to cover the operative wound. In our ROADSTER clinical study, 53% of TCAR procedures were performed under local anesthesia. In addition, multiple analyses of real-world data from the Society for Vascular Surgery's TCAR Surveillance Project showed a statistically significant reduction in the likelihood that a TCAR patient would require a hospital stay in excess of one day as compared to a CEA patient.

- ***Reduction in the risk of microembolic debris.*** While large emboli have dominated clinical focus and discussion due to the ability to cause clinically diagnosed stroke or TIAs, there is a growing body of evidence that indicates that showers of micro emboli to the brain, which, for example, may be caused by the CAS procedure, can cause neurologic injuries including memory loss, cognitive decline and dementia, while increasing the risk of future stroke. Data from our PROOF clinical trial indicated that only 18% of studied TCAR patients presented with new white lesions occurring on the same side of the brain, or ipsilateral, as the treated carotid artery, as shown on diffusion-weighted magnetic resonance imaging studies. This rate of new white lesions, which indicate brain injury, was comparable to published data for CEA procedures and significantly lower than published data for CAS procedures, which show a range of 45% to 87% of patients with new white ipsilateral lesions.

- ***Short adoption curve for physicians new to TCAR.*** In a publication from the TCAR Surveillance Project in January 2020, 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. 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. The incidence of stroke and death was not statistically significantly different for novice practitioners (1.5%) compared to expert practitioners (1.4%; p=0.90).

We believe the results of our clinical studies provide evidence that TCAR may offer significantly better reduction in stroke risk than CAS and similar reduction in stroke risk compared to CEA, the current standard of care for carotid revascularization, allowing physicians to present the minimally-invasive alternative of TCAR to patients without compromising the reduction in stroke risk they would expect in a CEA procedure. We believe the growing clinical evidence base from our ongoing and future studies and the Society for Vascular Surgery's TCAR Surveillance Project will continue to drive confidence in the procedure and support continued adoption.

Benefits to Other Key Stakeholders

In addition to offering clinical benefits to patients, we believe that TCAR also offers valuable non-clinical benefits for providers and payers relative to CEA and CAS.

Providers

We believe TCAR allows for improved hospital workflow given the simplicity, predictability, and efficiency of the procedure as compared to CEA and CAS. By allowing direct access to the carotid artery rather than requiring the physician to navigate the vasculature as in CAS, and allowing the physician to place a stent to trap plaque rather than requiring the time-consuming and physically burdensome surgical removal of carotid plaque as in CEA, we believe TCAR is a more efficient and predictable procedure. Data from the Society of Vascular Surgery's TCAR Surveillance Project has shown that the average TCAR procedure time has been statistically significantly shorter and that there has been a statistically significant reduction in the percent of hospital stays longer than one day, relative to CEA. These benefits can help hospitals to better utilize their operating room capacity and fixed overhead and reduce the number of procedures associated with hospital stays longer than one day, which could result in financial losses for hospitals. We believe the economic benefits are further aided by the reduction in expensive adverse events that are borne by capitated providers or absorbed within 90-day global periods related to hospital reimbursement. Through third-party consultants, we have performed economic analyses of TCAR using our own clinical data from the ROADSTER study and published data for CEA surrounding cost inputs for both procedures and national weighted average reimbursement rates. We believe the results of these analyses show that TCAR compares favorably to CEA in terms of hospital margins and economic value proposition for the procedure itself as well as the full length of hospital stay.

Payers

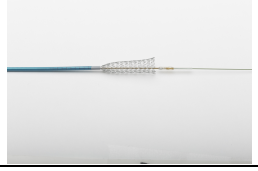
Stroke is one of the costliest conditions for the healthcare system and ranked in the top ten most expensive conditions for Medicare, Medicaid, and private insurers in 2013. By reducing the 30-day stroke risk from the procedure and the long-term stroke risk from the disease after 30 days, we believe that TCAR mitigates the significant cost burden associated with the morbidity of stroke victims. In addition to reducing costs associated with stroke, we believe TCAR also helps to reduce downstream costs associated with cranial nerve injuries, myocardial infarction, microembolization and other adverse events.

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 with clinical data regarding lasting safety outcomes • 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

Our ENROUTE NPS and ENROUTE stent are FDA cleared and approved, respectively. The ENROUTE NPS 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.

Our Target Market

We are working to establish TCAR as the preferred alternative to both CEA and CAS for the treatment of patients with carotid artery disease. Because TCAR offers clinically proven, minimally-invasive reduction in stroke risk, we believe that TCAR can offer a better solution for the approximately 168,000 patients treated in the United States in 2018, most of whom were treated with either CEA or CAS, which we estimate to be a near-term market conversion opportunity greater than $1.0 billion. Additionally, we believe that as our technology becomes more widely adopted, TCAR may become a compelling alternative for patients that are treated with medical management alone each year. As a result, we believe the potential addressable opportunity for TCAR includes the approximately 427,000 individuals in the United States who were diagnosed with carotid artery disease in 2018, representing a total U.S. target market opportunity of approximately $2.6 billion in 2018.

Currently, our ENROUTE stent is indicated for use in patients who are considered high surgical risk, and either are symptomatic with greater than or equal to 50% stenosis or are asymptomatic with greater than or equal to 80% stenosis. The labeled indications for use for our other products, including the ENROUTE NPS, are agnostic to surgical risk status. Based on the FDA label of high surgical risk for our stent, CMS provides reimbursement coverage for TCAR in patients who are considered a high surgical risk but not standard surgical risk. According to published studies and primary research, we believe the high surgical risk population represents approximately two-thirds, or over 111,000, of the approximately 168,000 patients treated for carotid artery disease in the United States in 2018, most of whom were treated with either CEA or CAS. We are currently focused on clinical development activities to support

label expansion for our ENROUTE stent to standard surgical risk patients. We would then seek an associated expansion in CMS reimbursement coverage.

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 intend to pursue regulatory clearances or approvals in China, Japan, and other select international markets. Carotid artery disease and stroke are prevalent, devastating and costly conditions worldwide, and we estimate that a significant opportunity exists for TCAR outside the United States, since the United States represents only 10% of the estimated global incidence of ischemic stroke.

Our Growth Strategy

Our mission is to be the global leader in the treatment of carotid artery disease. We seek to improve the standard of care for carotid revascularization by targeting the market for CEA and CAS procedures and expanding the application and regulatory authorization for our TCAR products to include patients treated with medical management alone. Our growth strategies include:

- ***Strategically expanding our U.S. sales force and marketing activities***. As of December 31, 2019, we have approximately 640 hospital accounts across 33 active sales territories. To date, we have taken a measured approach to account targeting and physician training. Over time, we plan to selectively add highly qualified personnel to our commercial organization with a strategic mix of selling professionals and clinical specialists to cover the concentrated group of approximately 2,750 physicians and 750 hospitals that we believe perform 80% of carotid revascularization procedures. As we grow the size of our U.S. sales organization, we plan to remain focused on educating hospitals and physicians regarding the benefits of TCAR and the expanding clinical evidence base, which we believe will increase the adoption of TCAR in existing hospital accounts while expanding our new account and trained physician base.

- ***Scaling professional education to drive physician use.*** As of December 31, 2019, we have trained approximately 1,440 physicians in the United States. Our education and training courses are led by a highly regarded faculty of key opinion leaders in vascular surgery, allowing for significant peer-to-peer interaction and influence from experienced TCAR practitioners. These courses have been fully subscribed since inception. We believe these professional education initiatives are a key differentiator in driving successful outcomes during the learning curve of TCAR and establishing the confidence physicians need to adopt TCAR. We plan to continue conducting these courses while regionalizing the course locations, continuously improving the program, and expanding our physician faculty.

- ***Increasing TCAR adoption.*** In our existing account and trained physician base, we have shown an ability to drive adoption in high surgical risk patients where CEA might otherwise be riskier or technically challenging, as well as in patients with anatomy or risk factors unfavorable for CAS. Our strategy is to continue educating physicians in the approved indications for our TCAR products, and to expand the approved uses of our products across broader patient subgroups, as physicians' experience and confidence with the procedure accrues and our clinical evidence base expands through the Society for Vascular Surgery's TCAR Surveillance Project and our ongoing and future studies. We also plan to continue converting CEA or CAS procedures to TCAR in current hospital accounts by training additional physicians in these accounts.

- ***Building our clinical evidence base***. Vascular surgeons typically rely on clinical evidence to drive changes in their practice. Primary care physicians and specialist referrers like neurologists and cardiologists also scrutinize clinical evidence. We completed the ROADSTER 2 study in 2019 and the results were subsequently presented in June 2019 at the VAM in National Harbor, Maryland, and we expect the data to be published in a peer-reviewed medical journal in the future. We plan to continue to build our clinical evidence base by commencing new clinical studies intended to support marketing efforts and regulatory initiatives. We also expect the

Society for Vascular Surgery's ongoing TCAR Surveillance Project registry to continue to grow and produce valuable presentations and published papers with comparative data and sub-group analyses that will further define the role of TCAR across patient populations.

- ***Broadening the indication for the ENROUTE stent and expanding reimbursement.*** We plan to continue to work to expand FDA labeling for the ENROUTE stent to address the approximately one-third of treated patients who present standard surgical risk. If we obtain approval of a label expansion, we intend to pursue Medicare coverage for TCAR in standard surgical risk patients.
- ***Pursuing international markets.*** Carotid artery disease and stroke are prevalent, devastating and costly conditions worldwide, and we estimate that a significant opportunity exists for TCAR outside the United States. We currently have CE Mark for the ENROUTE NPS and ENROUTE stent, which would allow us to commercialize in Europe in the future. We are also actively working towards regulatory clearances for our products in China and Japan.
- ***Continuing our history of innovation in and beyond TCAR.*** We are currently developing additional and next generation products to support and improve TCAR to meet the evolving needs of physicians and their patients. We also have a broad intellectual property platform and, in the future, we intend to leverage our expertise and the physiologic and engineering advantages made possible by our transcarotid approach to develop new products targeting procedures and vascular disease states in the heart, aortic arch and brain.

Clinical Data

The safety, effectiveness and clinical advantages of TCAR have been observed in multiple clinical trials and post-market studies that have collectively evaluated more than 11,900 patients in the United States and Europe 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 which includes over 8,100 patients treated with TCAR as of December 31, 2019.

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	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	Enrolling >8,100 patients as of December 31, 2019
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	ROADSTER - pivotal phase		ROADSTER - continued access		Pooled ROADSTER	
	ITT population	ITT population	Per-protocol	ITT population	Per-protocol	ITT population	Per-protocol
Stroke at 30 days							
All stroke[1]	1.3 %	1.4 %	0.7 %	1.3 %	0.0 %	1.4 %	0.5 %
All stroke and death	1.3 %	2.8 %	2.2 %	1.3 %	0.0 %	2.3 %	1.5 %
Other adverse events at 30 days							
Myocardial infarction	0.0 %	0.7 %	0.7 %	2.6 %	1.5 %	1.4 %	1.0 %
Cranial Nerve Injury *(Acute)*	2.7 %	0.7 %	NR	0.0 %	NR	0.5 %	NR
Cranial Nerve Injury *(persisting at 6 months)*	2.7 %	0.0 %	NR	0.0 %	NR	0.0 %	NR
Procedural information							
Mean procedure time (mins)	NR	73.6	NR	72.4	NR	73.2	NR
Mean length of stay *(days)*	NR	1.9	NR	1.4	NR	1.7	NR

(1) All strokes observed have been minor strokes; No major strokes have been observed.

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 stroke incidence of 1.3% within 30 days, 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 in patients with a life expectancy of 1 year.

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 PP basis, is 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 that 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.

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 combined pivotal and continued access cohorts of the initial ROADSTER study. Other key clinical endpoints include the rates of hierarchical ipsilateral stroke, death and myocardial infarction, cardiac death, neurologic death and cranial nerve injury. These key clinical endpoints in ROADSTER 2 are summarized in the following table:

ROADSTER 2: key clinical endpoints at 30 days

	N=632
Stroke and death at 30 days	
All stroke	0.6 %
All stroke and death	0.8 %
Other adverse events at 30 days	
Ipsilateral Stroke	0.5 %
Rate of Death - Cardiac	0.0 %
Rate of Death - neurologic	0.0 %
Rate of Death - Other	0.2 %
Rate of Acute Cranial Nerve Injuries (ITT)	1.4 %
Myocardial infarction	0.9 %
Procedural information	
Mean procedure time (mins)	74.6
Mean length of stay (days)	1.6

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 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 it is available to all providers of vascular health care and their respective institutions. Because data from CAS procedures are also collected in the Society for Vascular Surgery VQI, comparisons of TCAR to CAS 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 carotid artery stenting 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.

In the Society for Vascular Surgery Vascular Quality Initiative 2019 Annual Report, it was reported that 292 centers have contributed more than 8,100 TCAR cases to the CAS VQI registry. In an article for *Endovascular Today*, in August 2019, Marc Schermerhorn, M.D. reported that TCAR accounted for more than 50% of the procedures entered into the CAS registry of the SVS VQI in the first four months of 2019. In an email from the TCAR steering committee, they further projected that TCAR would account for more than 4,000 procedures during 2019 while CAS would account for just over 3,000 procedures.

TCAR Surveillance Project: TCAR vs. CEA

Contemporaneous comparative outcomes from January 2016 to September 2018 were presented in November 2018 in both unadjusted analyses as well as analyses adjusted for the baseline characteristics of the patient populations. In general, patients treated with TCAR were older than patients treated with

CEA, and were more likely to have coronary co-morbidities, renal dysfunction and a prior carotid intervention. Below is a summary of the outcomes presented and the patient demographics in which there was a statistically significant difference between the populations.

TCAR vs. CEA Unadjusted Outcomes (in hospital)

Stroke and other adverse events	TCAR (%) N=2,545	CEA (%) N=43,114	P-value
Major adverse events at 30 days			
Stroke/Death	1.8	1.4	0.09
Stroke/Death/Myocardial infarction	2.1	1.8	0.17
Stroke	1.4	1.2	0.27
Death	0.5	0.3	0.04
30-day Death	0.9	0.6	0.08
Other adverse events at 30 days			
Myocardial infarction	0.4	0.4	0.71
Cranial nerve injury	0.2	2.7	<.001
Bleeding	1.4	1.0	0.05
Other procedural information			
Mean procedure time (mins)	75.0	116.0	<0.001
Length of stay >1 day	29 %	32 %	<0.01

TCAR vs. CEA Baseline Demographics (% of patients)

	TCAR N=2,545	CEA N=43,114	P-value
Age	73.1 + 9.4	70.6 + 9.6	<.001
Female	36.2 %	39.4 %	<.01
Coronary artery disease	51.3 %	26.9 %	<.001
Prior congestive heart failure	18.8 %	11.2 %	<.001
Prior coronary artery bypass grafting	23.7 %	19.8 %	<.001
Prior percutaneous coronary intervention	28.2 %	22.1 %	<.001
Chronic obstructive pulmonary disease	29.2 %	23.2 %	<.001
Glomerular filtration rate<60	40.6 %	34.3 %	<.001
Current smoker	23.5 %	25.3 %	0.05
Prior carotid revascularization	30.7 %	15.0 %	<.001
Aspirin	89.8 %	83.9 %	<.001
Antiplatelet	84.7 %	34.5 %	<.001
Statin	88.3 %	83.4 %	<.001
Beta-blockers	55.1 %	51.0 %	<.001
Anticoagulants	13.4 %	10.4 %	<.001
Anesthesia	82.7 %	92.3 %	<.001

The unadjusted results to date from the TCAR Surveillance Project show that TCAR has provided similar in-hospital reduction in stroke risk as compared to CEA, despite treating sicker, older patients with TCAR, and TCAR showed significantly lower risk of cranial nerve injury. The incidence of in-hospital

death in the unadjusted outcomes was slightly higher for TCAR due to the co-morbidities in the TCAR patients. Patients treated with TCAR were generally older and had more co-morbidities than the cohort of patients treated with CEA. As such, the odds ratio of in-hospital death between TCAR and CEA is the same when adjusting for patient risk factors.

In the unadjusted analysis, cranial nerve injury and bleeding were significantly different between TCAR and CEA. TCAR patients had a ten-fold reduction in risk of cranial nerve injury when compared to CEA, and TCAR had a significantly higher rate of bleeding. When adjusting for risk and in a propensity matched analysis, the rate of bleeding was not significantly different between TCAR and CEA; however, the significantly lower risk of cranial nerve injury with TCAR remained.

Average TCAR procedure time was significantly shorter and there was a significant reduction in the percentage of hospital stays longer than one day, relative to CEA. These benefits can help hospitals to better utilize their operating room capacity and fixed overhead and reduce the number of procedures associated with hospital stays longer than one day, which have been shown to result in financial losses for the hospital facilities.

TCAR Surveillance Project: TCAR vs. CAS

In a similar analysis comparing TCAR to CAS, TCAR showed significantly lower rates of stroke and death; stroke, death and myocardial infarction; in hospital death; and death within 30 days in both the adjusted and unadjusted analysis. When adjusted for baseline risk characteristics associated with the patient population, the difference in bleeding events was no longer significant. Below is a summary of the outcomes presented and patient demographics for patient characteristics with a statistically significant difference between the populations.

TCAR vs. CAS Unadjusted Outcomes (in hospital)

Stroke and other adverse events	TCAR (%) N=2,545	CAS (%) N=9,460	P-Value
Stroke/Death	1.8	3.3	<.001
Stroke/Death/Myocardial infarction	2.1	3.5	<.001
Stroke	1.4	2.2	0.02
In-hospital Death	0.5	1.4	<.001
30-day Death	0.9	2.0	<.001
Myocardial infarction	0.4	0.3	0.62
Bleeding	1.4	0.6	<.001

TCAR vs CAS Baseline Demographics (% of patients)

	TCAR N=2,545	CAS N=9,460	P-Value
Age	73.1 + 9.4	69.6 + 3.7	<.001
Black	4.5 %	6.1 %	<.01
Asymptomatic	52.3 %	38.1 %	<.001
Coronary artery disease	51.3 %	38.9 %	<.001
Prior congestive heart failure	18.8 %	16.6 %	<.01
Prior coronary artery bypass grafting	23.7 %	20.8 %	<.01
Prior percutaneous coronary intervention	28.2 %	25.7 %	0.01
Chronic obstructive pulmonary disease	29.2 %	27.0 %	0.03
Glomerular filtration rate<60	40.6 %	34.5 %	<.001
Current Smoker	23.5 %	28.5 %	<.001
Prior CEA	25.1 %	28.2 %	<.01
Prior CAS	8.0 %	19.3 %	<.001
Aspirin	89.8 %	85.1 %	<.001
Antiplatelet (other than aspirin)	84.7 %	74.7 %	<.001
Statin	88.3 %	81.6 %	<.001
Beta-blockers	55.1 %	52.6 %	0.03
Anticoagulants	13.4 %	11.7 %	0.02
Medical high risk	59.4 %	36.0 %	<.001
Anatomic high risk	50.6 %	43.8 %	<.001
General Anesthesia	82.7 %	20.0 %	<.001

Since November 2018, the TCAR Surveillance Project Steering Committee has presented and published updated comparisons of TCAR to both CEA and CAS. In June 2019, updated outcomes from the TCAR Surveillance Project were presented at VAM. The outcomes featured data from 5,716 patients treated with TCAR and 44,442 patients treated with CEA. In a propensity matched analysis of TCAR and CEA with 5,160 patients in each cohort, TCAR provided similar in-hospital stroke rates as compared to CEA, but had significantly lower odds of in-hospital myocardial infarction and composite stroke, death and myocardial infarction. TCAR patients were also significantly less likely to suffer a cranial nerve injury and to remain in the hospital longer than one day. TCAR had lower odds of 30-day death (34% lower), 30-day myocardial infarction (64% lower), 30-day stroke and death (46% lower), and composite stroke, death and myocardial infarction (53% lower).

	Propensity Score Matching (N=5,160 in each cohort)	
	OR (95% CI)	*P-value*
In-Hospital Outcomes		
Death	0.86 (0.46-1.61)	0.63
Ipsilateral Stroke	0.92 (0.64-1.32)	0.64
Stroke	0.80 (0.58-1.11)	0.19
MI	0.41 (0.26-0.66)	<**0.001**
Stroke/Death	0.77 (0.57-1.04)	0.09
Stroke/Death/MI	0.65 (0.50-0.84)	**<0.01**
Cranial Nerve Injury	0.13 (0.07-0.22)	**<0.001**
Post-procedural Hypotension	1.66 (1.47-1.87)	**<0.001**
Post-procedural Hypertension	0.64 (0.57-0.71)	**<0.001**
Bleeding with intervention	1.17 (0.83-1.65)	0.38
Non-Home discharge	0.75 (0.64-0.87)	**<0.001**
Hospital Stay for more than 1 day	0.74 (0.68-0.80)	**<0.001**

30-Day Outcomes	**Unadjusted**			**Adjusted**		
	CEA	TCAR	P-value	CEA	TCAR	P-value
Mortality	308 (0.70)	40 (0.70)	0.95	Ref.	0.66 (0.46-0.95)	**0.03**
Stroke	241 (1.4)	16 (1.1)	0.46	Ref.	0.68 (0.39-1.20)	0.18
MI	140 (0.80)	9 (0.6)	0.52	Ref.	0.36 (0.16-0.83)	**0.02**
Stroke/Death	323 (1.8)	19 (1.4)	0.19	Ref.	0.54 (0.33-0.89)	**0.02**
Stroke/Death/MI	453 (2.6)	27 (1.9)	0.13	Ref.	0.47 (0.30-0.74)	**<0.01**

In December 2019, the steering committee of the TCAR Surveillance Project published a comparison of outcomes for TCAR and CAS in the *Journal of the American Medical Association*. During the study period (September 2016 through May 2019), 5,251 patients underwent TCAR and 6,640 patients underwent CAS. After propensity score matching, there were 3,286 pairs of patients available for analysis. As was the case in the VAM presentation comparing TCAR and CEA, TCAR patients were older and had more medical co-morbidities. In-hospital stroke or death was 1.6% for TCAR versus 3.1% for CAS. TCAR was associated with significantly lower risks of in-hospital stroke alone (1.3% for TCAR versus 2.4% for CAS) and in-hospital death alone (0.4% for TCAR versus 1.0% for CAS). The differences favoring TCAR persisted through 30 days and 1 year. Key clinical and procedural outcomes are summarized in the following table:

Outcome	TCAR (n=3,286)	CAS (n=3,286)	Relative Risk (95% CI)	*P* Value
Stroke or death (in hospital)	1.6%	3.1%	0.51 (0.37 to 0.72)	<.001
Stroke or death (30 days)	1.9%	3.7%	0.54 (0.38 to 0.79)	<.001
Stroke or death (1 year)	5.1%	9.6%	0.52 (0.41 to 0.66)	<.001
Stroke (in hospital)	1.3%	2.4%	0.54 (0.38 to 0.79)	0.001
Stroke (30 days)	1.3%	2.5%	0.53 (0.37 to 0.76)	<.001
Death (in hospital)	0.4%	1.0%	0.44 (0.23 to 0.82)	0.008
Death (30 days)	0.8%	1.5%	0.52 (0.32 to 0.84)	0.007
Myocardial Infarction	0.2%	0.3%	0.70 (0.27 to 1.84)	0.47
Access site bleeding complication	3.5%	3.8%	0.93 (0.72 to 1.19)	0.55
Interventional treatment	1.3%	0.8%	1.63 (1.02 to 2.61)	0.04
Blood transfusion	1.8%	2.2%	0.85 (0.60 to 1.19)	0.33
Technical Failure	0.5%	1.2%	0.37 (0.20 to 0.66)	<.001

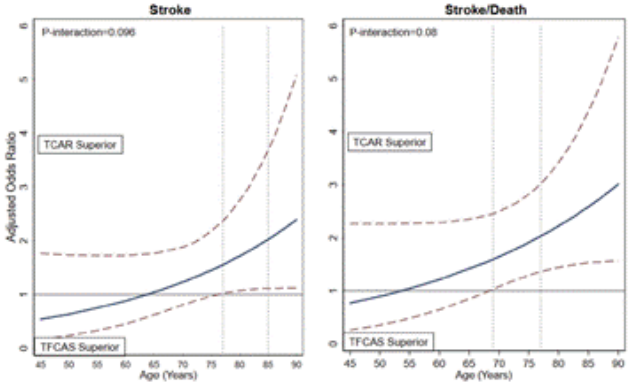
In another publication from the SVS VQI published in the Journal of the American College of Surgeons in January 2020, Kashyap, et al, examined the learning curve of TCAR performed by surgeons participating in the TCAR Surveillance Project. The authors reviewed 3,456 TCAR procedures performed by 417 unique 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. The following table summarizes unadjusted outcomes by surgeon case experience:

Outcome	Novice Cases 1-5 (n=1,426)	Intermediate Cases 6-20 (n=1,375)	Advanced Cases 20-30 (n=307)	Expert Cases >30 (n=348)	*P* Value
Stroke/death	1.5%	1.4%	2.0%	1.4%	0.9
Stroke/death/MI	1.8%	1.6%	2.0%	2.3%	0.84
Stroke	1.2%	1.2%	1.0%	1.2%	0.99
TIA	0.8%	1.0%	0.7%	0.3%	0.65
Death	0.3%	0.4%	1.0%	0.6%	0.39
MI	0.4%	0.2%	0.0%	0.9%	0.2
Cranial nerve injury	0.2%	0.4%	0.0%	0.0%	0.51
Bleeding complications	3.9%	3.4%	1.6%	1.2%	0.03
Technical Failure	0.5%	0.7%	0.3%	0.0%	0.45

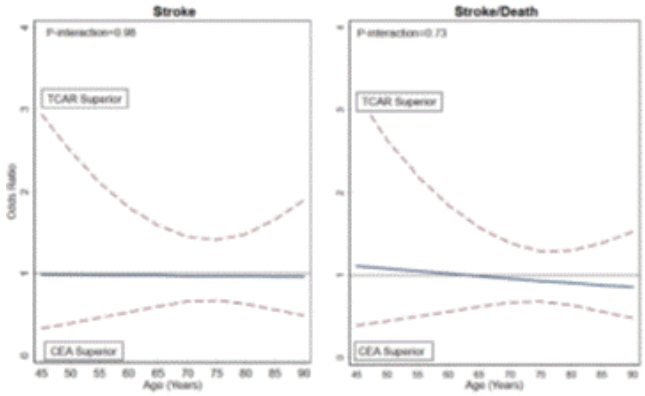
In January 2020, the SVS VQI published data on the impact of age on in-hospital outcomes after TCAR, CAS and CEA in the *Journal of Vascular Surgery*. Patients entered in the SVS VQI CAS and CEA registries between 2015 and November 2018 were included in the analysis. The study cohort included 3,152 TCAR patients, 10,381 CAS patients and 61,650 CEA patients. Patients were divided into three age groups (≤70 years, 71-79 years and ≥80 years). As was the case in previous analyses from the SVS VQI, TCAR patients were older and more likely to have major co-morbidities such as coronary artery disease, congestive heart disease, chronic kidney disease and a higher ASA classification. Over 25% of the TCAR patients were 80 years of age or older compared to 15.8% of CAS patients and 17.6% of CEA patients.

The rates of in-hospital stroke/death after TCAR were 1.4% in patients ≤70 years, 1.9% in patients 71-79 years and 1.5% in patients ≥80 years. The differences between age groups were not significant (p=0.55). The comparison of TCAR to CEA across different age groups showed no differences in outcomes and no interaction between treatment and age in predicting in-hospital stroke/death (p=0.80). As with prior analyses, TCAR had significantly lower odds of cranial nerve injury compared to CEA across the three age groups (84%, 79% and 95% respectively).

Conversely, in patients age >/+80, TCAR was associated with a 72% reduction in stroke risk (1.0% vs 4.7%; OR 0.28; 95%CI, 0.12-0.65; p<0.01), a 65% reduction in the risk of stroke/death (1.5% vs 4.6%; OR 0.35; 95%CI 0.20-0.62; p<0.001) and a 76% reduction in stroke/death/myocardial infarction (2.5% vs 5.3%; OR 0.24; 95%CI 0.12-0.47; p<0.001) when compared to CAS. The stroke risk for CAS doubled at age 85 compared to TCAR; the stroke/death risk for CAS doubled at age 77 compared to TCAR. No significant differences were noted between TCAR and CEA with age.



Adjusted odds ratios (ORs) of in-hospital stroke (left) and stroke/death (right) after TCAR vs CAS for age-by-treatment interaction. In each graph, the first dotted vertical line represents the age at which the odds of the outcomes in CAS compared with TCAR become significant. The second dotted vertical line represents the age at which the odds in CAS become double that of TCAR.



Adjusted odds ratios of in-hospital stroke (left) and stroke/death (right) for age-by-treatment (CEA vs TCAR) interaction.

The authors attributed the significant increase in odds of adverse outcomes after CAS compared with TCAR in patients ≥80 years of age to the increased prevalence of severe aortic arch disease and target lesion calcification and ulceration in the elderly. The authors concluded that TCAR is relatively safe regardless of patient age independent of symptomatic status and other medical comorbidities.

Ongoing and Planned TCAR Studies

In addition to the Society for Vascular Surgery's TCAR Surveillance Project, we have one ongoing study in the European Union enrolling up to 50 patients and evaluating the rate of sub-clinical embolization, or new white lesions, as detected on DW-MRI in recently symptomatic patients. The primary endpoint is the rate of ipsilateral new white lesions as seen on DW-MRI at 30 days compared to pre-procedure baseline white lesions. The evaluation of the presence of new white lesions is conducted in a blinded fashion by an independent neuroradiologist.

We are conducting a similar study at four hospitals in the United States and one in the European Union. We have obtained Institutional review board and ethics committee approvals and enrollment began in the third quarter of 2019. The primary endpoint is the rate of ipsilateral new white lesions at 30 days. Enrollment of up to 75 patients is planned in this study.

Our Commercial Strategy

We designed our commercial strategy and built our direct sales force to target primarily vascular surgeons across the United States, who we believe represent the specialty most frequently responsible for managing the care of and receiving referrals for patients with carotid artery disease. We believe there are approximately 2,750 physicians that perform an estimated 80% of annual carotid revascularization procedures in the United States. Vascular surgeons are skilled in endovascular procedures and 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 for TCAR through a direct sales organization consisting of 35 sales representatives, known as area managers, or AMs, and

61 clinical support specialists, known as therapy development specialists, or TDSs, as of December 31, 2019. 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 also selectively provide training through physician proctors on an as needed basis. As of December 31, 2019, we have trained and certified over 1,440 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 in-person 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 successfully launched our products, driven adoption of TCAR and made significant progress securing reimbursement codes and payer coverage.

During the ROADSTER trial, the Society for Vascular Surgery helped to guide modifications of existing 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 Healthcare Utilization Project, Medicare is the primary payer for carotid revascularization procedures, representing approximately 78% of the payer mix for CEA and CAS procedures in 2014. 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, with the exception of 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. The proper ICD-10-PCS

procedure codes for TCAR are 037H3DZ, 037J3DZ, 037K3DZ and 037L3DZ, and the appropriate MS-DRGs for TCAR are 034 when the patient presents with major complications or co-morbidities, 035 when the patient presents with a complication or co-morbidity, and 036 for patients without complications or co-morbidities.

Payment for Physicians

The 2020 national average physician professional fee payment for CPT code 37215 is approximately $1,050. 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 2020 national average physician professional fee payment is $1,187.

Payment for Hospitals

The national unadjusted 2020 payment amounts for MS-DRGs 034, 035 and 036 are $23,512, $14,427 and $10,968 respectively. Based on prior procedure volumes, we estimate that the average payment amount across these three codes is $13,850 in 2020. These single MS DRG payments are intended to cover all hospital costs associated with treating an individual during his or her hospital stay, with the exception of 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 carotid artery disease. CEA procedures are reimbursed under MS-DRGs 037, 038 and 039. We expect the national unadjusted 2020 payment amounts for MS-DRGs 037, 038 and 039 to be $20,315, $10,493 and $7,086 respectively. Based on prior procedure volumes, we estimate that the average payment amount across these three codes to be $9,360. The base payment amounts for MS-DRGs may vary greatly by individual acute-care hospital for a number of reasons including but not limited to geographic, teaching status, case-mix index, and use of electronic health record systems.

Coverage

According to the Healthcare Utilization Project, the Center for Medicare and Medicaid Services, or CMS, was the primary payer for carotid procedures, covering 78% of CEA procedures and 77% of CAS procedures in 2014. In 2015, we also confirmed with CMS that TCAR, like CAS, was considered under the purview of the National Coverage Determination, or NCD, for Percutaneous Transluminal Angioplasty. Coverage of TCAR by CMS, other government, and commercial payers is important for our commercial development. Currently, pursuant to the NCD for Percutaneous Transluminal Angioplasty, TCAR is covered by CMS under certain circumstances for high surgical risk patients; as well as certain other instances, including participation in certain trials and studies.

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 TCAR Surveillance Project is an FDA-approved extension study. We understand that Medicare has reimbursed hospitals and physicians for symptomatic patients with greater than or equal to 50% carotid artery stenosis and asymptomatic high surgical risk patients with greater than or equal to 80% carotid artery stenosis who participate in the TCAR Surveillance Project. For billing purposes, facilities and providers can submit claims for the TCAR Surveillance Project using National Clinical Trial identifier NCT02850588.

ROADSTER 2 is another FDA-approved Post Approval Study that was completed in 2019. Patients who met the inclusion/exclusion criteria for ROADSTER 2 were eligible for CMS coverage under the NCD under certain circumstances. Providers billed the Pre-Market Approval number assigned to the stent system by the FDA, P140026, to obtain reimbursement.

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 will include 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 such as Enrique Criado M.D., and David Chang M.D., the pioneers of TCAR, 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 the completion of our ROADSTER 2 Post Approval Study, our current clinical program consists of ongoing studies in the European Union and United States to evaluate the rate of sub-clinical embolization as detected through DW-MRI in recently symptomatic patients. We expect to utilize the results of these clinical studies to support our marketing efforts and encourage continued adoption of TCAR.

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, 2019 and 2018, our research, development and clinical expenses were $12.3 million and $10.3 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 Cardinal. Other companies have approved devices not currently marketed in the United States, including Gore and InspireMD. Additionally, some companies have stents and other products under development for use in CAS procedures, including Terumo. Most 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, 2019, we owned 76 patents globally, of which 53 were issued U.S. patents and 23 were patents outside of the United States. Our patents expire between November 2024 and December 2034. 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
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, 2019, we had 57 pending patent applications globally, including 29 in the United States and 28 outside the United States.

As of December 31, 2019, we had trademark registrations for “Silk Road Medical,” the “Silk Road Medical” logo, “Enroute” and the “Enroute” logo and “Enhance” in the United States, and various other countries. Including these trademark registrations, our trademark portfolio contained 24 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 and distribute all of our products from 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. While we believe our existing facility will be sufficient to meet our manufacturing needs for at least the next four years we intend to supplement our distribution operations with a third-party logistics and warehousing service and/or additional leased facilities.

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. When the new EU Medical Regulations take effect in May 2020, 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. 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 recall of our products, which would 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.

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 have initiated a Corrective and Preventive Action, or CAPA, that we believe addresses the single FDA Observation. 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 September 2017, 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. Cardinal 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 implement 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 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, the British Standards Institution, or 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 Medical Device Directive, or 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. When the new EU Medical Regulations take effect in May 2020, 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 up to $104,330 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in 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 ranging from $11,665 and $23,331 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 may result in civil monetary penalties of up to $176,495 per annual report for failing to report payments in a timely manner. Knowingly failing to submit payment information may result in a civil money penalty of up to $1,176,638. 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. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the remaining provisions of the ACA are invalid. It is unclear how this decision, subsequent appeals, and other 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.

Employees

As of December 31, 2019, we had 224 full-time employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that our employee relations are good.

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, CA 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/) 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 condensed financial statements and related notes. Please also see "Cautionary Notes Regarding Forward-Looking Statements."

Risks Related to Our Business

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

We have incurred net losses since our inception in March 2007. For the years ended December 31, 2019 and 2018, we had a net loss of $52.4 million, and $37.6 million, respectively, and we expect to continue to incur additional losses in the future. As of December 31, 2019, we had an accumulated deficit of $191.5 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products that enable transcarotid artery revascularization, or TCAR. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure improvements.

We fully commercialized our products in the United States in 2016 and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue to devote a substantial amount of our resources to expand commercialization efforts and increase adoption of TCAR using our products, improve and expand reimbursement for TCAR, and develop additional products. In addition, as a newly public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's TCAR Surveillance Project contains real world data comparing procedures, we have not conducted head-to-head clinical trials to compare TCAR to the procedures historically available to patients, such as CEA or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis 2 clinical trial is currently being conducted by the National Institutes of Health, which compares the effectiveness of each of CEA and CAS with best medical management solutions. Although we estimate that enrollment will not be completed until 2022, 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 heavily influenced by medical society recommendations. We believe the Society for Vascular Surgery's Clinical Practice Guidelines, or SVS Guidelines, are of particular importance to the broader market acceptance of TCAR. The most current SVS Guidelines on the management of carotid artery disease, published in 2011, do not specifically mention TCAR as a treatment for carotid artery disease, but generally discuss CAS and embolic protection methods, including flow reversal. If the next version of the SVS Guidelines do not recommend TCAR, or if the Society for Vascular Surgery issues a negative or 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, physician organizations may adopt physician credentialing guidelines requiring TCAR training 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.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or coronavirus, may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs, our business may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of February 2020, has spread to over 50 countries, including the United States. Such events may result in a period of business and manufacturing disruption, and in reduced sales and operations, any of which could materially affect our business, financial condition and results of operations. For example, the spread of COVID-19 in the United States may result in travel restrictions impacting our sales professionals and therapy development specialists who support them. Travel restrictions may also reduce the number of physicians travelling to attend our training programs, which would result in fewer physicians trained on the TCAR procedure. In addition, hospitals may reduce staffing and postpone certain procedures in response to COVID-19 or divert

resources to treat those patients with an infectious disease. Hospitals may also limit access for non-patients, including our sales professionals and therapy development specialists, which would negatively impact our access to physicians and their patients. Any of the foregoing actions could adversely affect our sales and the revenue we derive as a result.

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. The spread of an infectious disease, including COVID-19, could result in the inability of our suppliers to deliver components or raw materials to us on a timely basis. If there were a shortage of supply, the cost of these materials or components may increase and harm our ability to provide our products on a cost-effective basis. In connection with any supply shortages in the future, 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 products. In the event that any of our suppliers were to discontinue production of our key product components, developing alternate sources of supply for these components would be time consuming, difficult and costly. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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

Our products enable TCAR, which is a novel procedure, and our success depends on acceptance of our products and TCAR by the medical industry, including physicians and hospitals. The FDA reviews our products 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 known. We have limited data on the ENROUTE stent and TCAR up to one year. Any failure of our stent or in-stent restenosis of the carotid artery following deployment of the stent could deter physicians from adopting our products and could have a material adverse effect on our business, financial condition and results of operations.

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

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

TCAR is currently covered under certain circumstances for certain patients by the Centers for Medicare and Medicaid Services, and has been covered by some commercial payers, independent networks and other entities not governed by the National Coverage Determination. In the United States, we derive our revenue from sales to hospitals and medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payers, including Medicare, Medicaid, 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 or our products, 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.

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

Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and

reimbursement are not available for 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 Cardinal Health, we could lose license rights that are important to our business.

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

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

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

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

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

Risks of TCAR using our products include the risks that are common to 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 have limited experience manufacturing our products in commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Sunnyvale, California, where we assemble and package certain of our products, and inspect, release and ship all of our products. We currently produce our ENROUTE NPS at this facility, and we and the contract manufacturers of our other products do not have redundant facilities. 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 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.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our 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 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 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 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;
- Difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- Inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- Inability to 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 existing threat of coronavirus, particularly as it may impact our supply chain should the slowdown in China persist.

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

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

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our 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 could be negatively affected by many factors, including our limited historical commercial experience regarding TCAR, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which would impair the strength of our brand. From time to time, we ship products with short shelf life to customers for procedures, and to the extent those products are not used and expire, we may exchange them, and this may materially and adversely affect our gross margin. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

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

Our quarterly and annual results of operations, including our revenue, net income or net loss and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the

value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

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

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

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 will need to obtain approval by the FDA for a label expansion of the ENROUTE stent in standard surgical risk patients and obtain corresponding reimbursement coverage expansion for TCAR. FDA approval of an ENROUTE stent label expansion will require additional data from clinical studies or registries, which we intend to pursue. However, there are no guarantees that we will be able to obtain such clinical data or FDA approval of a label expansion for the ENROUTE stent, or that any label expansion or additional reimbursement coverage will be sufficient to 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 may reduce market prices for our products and/or require administrative fees, thereby reducing our revenue and/or margins.

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

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

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

If we are 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 are actively looking for additional facilities to store finished goods and to supplement the shipping and receiving capacity of our main offices in Sunnyvale, California. We are also searching for additional space to provide offices for the employees we expect to hire in California. Finally, we are in the process of determining whether to supplement our distribution operations with third-party logistics and warehousing services and/or additional leased facilities in other parts of the country. There is competition for office, shipping and warehousing space in the San Francisco Bay area and we can provide no assurance that we will find additional space or that such space will be on reasonable terms or that we will be successful in our efforts to contract with third parties elsewhere to augment our logistics and warehousing capabilities. 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.

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

We currently maintain our research and development, manufacturing and 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 have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and, 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 facility could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current lease for our manufacturing facility expires in 2024, and our operations are growing at a pace that may require us to find a replacement or expansion facility 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.

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

We have limited experience marketing and selling our products. We currently rely on our direct sales force to sell our products in targeted geographic regions 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 sales force may subject us to higher fixed costs than those of companies with competing products, such as stents, that utilize independent third parties, which could place us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost effective manner is critical to achieving broad acceptance of our products and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. 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. 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, Cardinal Health, Medtronic, Terumo, Gore and InspireMD. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

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

- Greater financial and human capital resources;
- Significantly greater name recognition;
- Established relationships with vascular surgeons 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, our research and development programs, 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.

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 as of December 31, 2019, 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;
- The scope and timing of investment in physician training;
- The scope, rate of progress and cost of our current or future clinical studies;
- The scope, rate of progress and cost of our research and development activities;
- The scope, rate of progress and cost of additional regulatory clearances or approvals;
- The costs associated with any product recall that may occur;

- The costs of attaining, defending and enforcing our intellectual property rights;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

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

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business.

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

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

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

As of December 31, 2019, we had an aggregate of approximately $44.9 million in principal and interest outstanding under our term loan agreement. We must make significant interest only quarterly payments under the loan agreement, which has diverted and will continue to divert resources from other activities. Our obligations under the term loan agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, repurchase stock and make investments, in each case subject to certain exceptions. The covenants related to the term loan agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our term loan agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable,

either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

We may acquire other companies or technologies, 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 and are not involved in negotiations to do so, 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, 2019, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $167.9 million and $148.4 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.

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 have the right to affix the CE Mark to our products, allowing us to commercialize in Europe in the future. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international 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 intellectual property license with Cardinal Health, we do not have the right to sell the ENROUTE stent through distributors, which may be desirable as we expand internationally. If we fail to renegotiate our agreement with Cardinal Health to enable sale of the ENROUTE stent through international distributors, 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.

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 of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers’ databases or systems that could adversely affect our business.

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

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

improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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

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

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

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

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

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

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

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

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

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

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

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

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or

otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in 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 any patents or patent applications and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and

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

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

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

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

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

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

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

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

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

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

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

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

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands 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 Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013

and, due to subsequent legislative amendments to the statute, will remain in effect through 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 scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. They could result in reduced demand for our products or result in additional pricing pressure. Any such reforms could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition and results of operations. Changes and reforms in the European Union 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 up to $176,495 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in mandatory exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- The federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,655 to $23,331 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 of $11,766 per failure up to an aggregate of $176,495 per year (or up to an aggregate of $1.177 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Failure to comply with the HIPAA privacy and security standards when applicable can result in civil monetary penalties up to $59,522 per violation, not to exceed $1.79 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

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

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

we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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

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

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

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

In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, in order to clear the proposed device for marketing. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

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

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;

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

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

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at a minimum of 30 sites in the United States to evaluate the safety and effectiveness of our products in at least 600 subjects. We have completed enrollment in this study and submitted our final report to the FDA. On February 11, 2020 we received notice from the FDA of their review and that we have fulfilled the post-approval study requirement. Thereafter, the product labeling must be updated and submitted in a PMA supplement, including any adverse event data, from the post-approval study. Failure to 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. We recently identified the need to implement corrective actions to our complaint handling procedures, which may have caused a delay in timely submission of 20 MDR reports to the FDA since we began commercialization in 2015. As of January 31, 2020, we had filed 160 MDR reports with the FDA for adverse events including stroke, arterial dissection, stent thrombosis and wound complications.

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

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

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

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

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

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

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

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

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

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

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

requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

- The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:
- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- Changes in reimbursement by current or potential payers;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;

- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

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

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

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

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

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

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

The holders of an aggregate of 7,835,229 shares of our outstanding common stock, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

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

As of February 28, 2020, our directors, officers and each stockholder holding 5% or more of our outstanding common stock and their affiliates beneficially owned approximately 40.3% of our outstanding common stock in the aggregate. In addition, we are required to nominate and use commercially reasonable efforts to have a number of individuals proportionate to the number of shares of common

stock held by entities affiliated with Warburg Pincus & Co. compared to the number of shares of common stock outstanding, designated by Warburg Pincus & Co., elected to the board of directors. As a result, the above stockholders, and Warburg Pincus & Co., acting alone, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. We have not elected under the rules of the Nasdaq Stock Market to take advantage of the "controlled company" exemption to opt out of any corporate governance requirements, but this concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

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

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

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

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in 2018. These efforts focused on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe the measures described above will remediate the material weaknesses identified and strengthen our internal control over financial reporting. While we believe the steps taken in our remediation initiatives outlined above are sufficient to remediate the material weaknesses in internal control over financial reporting, our improvements, including the enhanced controls, have not operated for a sufficient period of time to demonstrate that the material weaknesses are fully remediated. As such, the remediation initiatives outlined above were not sufficient to fully remediate the material weaknesses in internal control over financial reporting for the year ended December 31, 2019. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

While we continue with our plan to remediate the material weaknesses, we cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate these deficiencies in internal control or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be

identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements, causing us to fail to meet our reporting obligations.

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting for the year ended December 31, 2020. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

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

During our evaluation of our internal control, if we are unable to remediate our material weaknesses or if we identify additional material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have an additional material weakness or significant deficiency 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.

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

We currently qualify as an “emerging growth company” under the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the

Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual revenue of more than $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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

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

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

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

stockholder for a period of three years following the date on which the stockholder became an “interested” stockholder. See “Description of Capital Stock.”

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

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

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

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

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

Our chief financial officer had not previously been the chief financial officer of a publicly traded company and our chief executive officer had not previously been the chief executive officer of a publicly traded company. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. We are required, pursuant to

Section 404, to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report after the completion of our initial public offering in April 2019, provide a management report on the internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm. If we are unable to remediate our material weaknesses or if we have an additional material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are implementing the process and documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

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

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

Item 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. Our operations are growing at a pace that may require us to find a replacement or expansion facility sooner. We believe that additional space can be obtained on commercially reasonable terms as needed.

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 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 Market.

	Year Ended December 31, 2019	
	High	Low
Second Quarter (beginning April 4)	$ 51.50	$ 30.87
Third Quarter	$ 49.89	$ 31.22
Fourth Quarter	$ 40.79	$ 27.83

Holders of Record

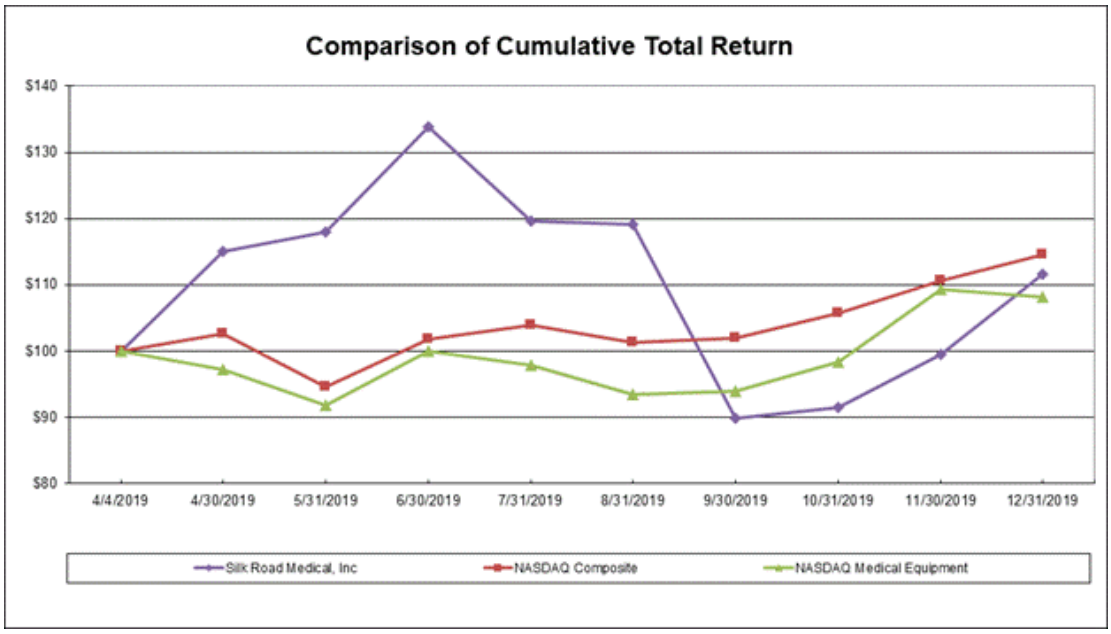
At February 28, 2020, there were approximately 91 stockholders of record of our common stock, and the closing price per share of our common stock was $39.85. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total 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.

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 Medical Equipment Index for the period from April 4, 2019 (the first day of trading of our common stock), through December 31, 2019. 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	April 4, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Silk Road Medical, Inc. (SILK)	$ 100	$ 134	$ 90	$ 112
NASDAQ Composite	$ 100	$ 102	$ 102	$ 115
NASDAQ Medical Equipment	$ 100	$ 100	$ 94	$ 108

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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

We derived the selected statements of operations data for the years ended December 31, 2019 and 2018 and the balance sheets data as of December 31, 2019 and 2018 from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. You should read this data together with our audited financial statements and related notes thereto included elsewhere in this and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data included in this section are not intended to replace the audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our future results.

Statements of Operations Data:

	Years Ended December 31,	
(in thousands, except share and per share data)	**2019**	**2018**
Revenue	$ 63,354	$ 34,557
Cost of goods sold	15,927	10,874
Gross profit	47,427	23,683
Operating expenses:		
Research and development	12,272	10,258
Selling, general and administrative	63,220	34,820
Total operating expenses	75,492	45,078
Loss from operations	(28,065)	(21,395)
Interest income (expense), net	(3,296)	(4,172)
Other income (expense), net	(21,054)	(12,063)
Net loss	(52,415)	(37,630)
Net loss attributable to non-controlling interest	—	1
Net loss attributable to Silk Road Medical, Inc. common stockholders	$ (52,415)	$ (37,629)
Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted	$ (2.28)	$ (39.16)
Weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted	22,956,679	960,882

Balance Sheets Data:

(in thousands)	As of December 31, 2019	2018
Cash and cash equivalents	$ 39,181	$ 24,990
Short-term investments	51,508	—
Working capital	95,558	27,824
Total assets	137,402	42,743
Long-term debt	44,879	44,201
Convertible preferred stock warrant liability	—	16,091
Convertible preferred stock	—	105,235
Accumulated deficit	(191,526)	(139,111)
Total stockholders' equity (deficit)	71,891	(134,553)

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 the section entitled "Selected financial data" and 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 also intend to pursue regulatory clearances in China, Japan, and other select international markets. TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG, classifications.

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

We manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We purchase our other products from third-party contract manufacturers, including our ENROUTE stent. Many of these third-party manufacturers and outside vendors are currently single-source suppliers. While we expect that our existing manufacturing facility will be sufficient to meet our anticipated growth through at least the next four years we intend to supplement our distribution operations with a third-party logistics and warehousing service and/or additional leased facilities.

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. As of December 31, 2019, we had cash and cash equivalents of $39.2 million, investments of $69.7 million, long-term debt of $44.9 million and an accumulated deficit of $191.5 million. Since inception, we have raised a total of $214.3 million in net proceeds from the sale of equity securities, including net proceeds of approximately $109.1 million from our initial public offering in April 2019.

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

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

	Three Months Ended							
	March 31, 2018	June 30, 2018	Sept. 30, 2018	Dec. 31, 2018	March 31, 2019	June 30, 2019	Sept. 30, 2019	Dec. 31, 2019
Number of U.S. procedures	774	1,008	1,243	1,548	1,724	1,997	2,255	2,458

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

Components of our Results of Operations

Revenue

We currently derive all of our revenue from the sale of our portfolio of TCAR products to hospitals and medical centers in the United States. 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, 2019 and 2018. We expect revenue to increase in absolute dollars as we expand our sales territories, new accounts and trained physician base and as existing physicians perform more TCAR procedures.

We expect our revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality. For example, in the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. 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 manufacture the ENROUTE NPS in California at our facility in Sunnyvale. We purchase our other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, direct labor, manufacturing overhead, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations

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

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, commercial operations and analytics, 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 the anticipated growth in revenue and due to additional legal, accounting, insurance and other expenses associated with being a public company. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

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 term loan agreement. We may, at our election, pay a portion of the interest on our term loan through the incurrence of additional indebtedness as payment-in-kind, or PIK. Our interest expense was partially offset by interest income earned on our investments.

Other Income (Expense), net

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

Results of Operations:

	Years Ended December 31,	
(in thousands)	**2019**	**2018**
Revenue	$ 63,354	$ 34,557
Costs of goods sold	15,927	10,874
Gross profit	47,427	23,683
Operating expenses:		
Research and development	12,272	10,258
Selling, general and administrative	63,220	34,820
Total operating expenses	75,492	45,078
Loss from operations	(28,065)	(21,395)
Interest income (expense), net	(3,296)	(4,172)
Other income (expense), net	(21,054)	(12,063)
Net loss	$ (52,415)	$ (37,630)

Comparison of Years Ended December 31, 2019 and 2018

Revenue. Revenue increased $28.8 million, or 83%, to $63.4 million during the year ended December 31, 2019, compared to $34.6 million during the year ended December 31, 2018. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $5.0 million, or 46%, to $15.9 million during the year ended December 31, 2019, compared to $10.9 million during the year ended December 31, 2018. This increase was attributable to the increase in the number of products sold and additional manufacturing overhead costs as we invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the year ended December 31, 2019 increased to 75%, compared to 69% in the year ended December 31, 2018. Gross margin increased as our production and ordering volumes increased and we were able to spread the fixed portion of our overhead costs over a larger number of units produced.

Research and Development Expenses. R&D expenses increased $2.0 million, or 20%, to $12.3 million during the year ended December 31, 2019, compared to $10.3 million during the year ended December 31, 2018. The increase in R&D expenses was primarily attributable to an increase of $1.4 million in personnel-related expenses including stock-based compensation, an increase of $0.3 million in clinical and regulatory expense, an increase of $0.3 million relating to educational grants, an increase of $0.2 million in product development materials and costs, an increase of $0.2 million in software related expense, and an increase of $0.1 million in outside services, partially offset by a decrease in travel and the allocation of facilities expense.

Selling, General and Administrative Expenses. SG&A expenses increased $28.4 million, or 82%, to $63.2 million during the year ended December 31, 2019, compared to $34.8 million during the year ended December 31, 2018. The increase in SG&A expenses is primarily attributable to an increase of $17.9 million in personnel-related expenses, an increase of $2.5 million in consulting, legal and professional fees, an increase of $2.2 million in marketing, tradeshow and promotional costs, an increase of $1.9 million in travel expenses, an increase of $1.3 million in insurance costs, an increase of $1.1 million in physician training and travel related costs, an increase of $0.8 million in software related expense, and an increase of $0.7 million relating to depreciation and the allocation of facilities and related expenses. Personnel-related expenses included stock-based compensation expense of $2.4 million and $0.6 million for the years ended December 31, 2019 and 2018, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.9 million, or 21%, to an expense of $3.3 million during the year ended December 31, 2019, compared to an expense of $4.2 million during the year ended December 31, 2018. This decreased expense was attributable to interest income earned on our investments, partially offset by the additional interest expense associated with the $15.0 million of additional borrowings in September 2018 under our term loan agreement. As of December 31, 2019 and 2018, the aggregate outstanding principal balance (including interest paid-in-kind) under the term loan agreement was $44.9 million and $44.2 million, respectively.

Other Income (Expense), Net. Other income (expense), net increased to an expense of $21.1 million during the year ended December 31, 2019, compared to an expense of $12.1 million during the year ended December 31, 2018. The decrease was primarily attributed to the remeasurement of our convertible preferred stock warrants and recognition of the change in fair value.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents of $39.2 million and investments of $69.7 million, an accumulated deficit of $191.5 million and $44.9 million outstanding under our term loan agreement. No borrowings remain available under this credit facility.

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.

Prior to our initial public offering, our primary sources of capital were private placements of convertible preferred stock, debt financing agreements and revenue from the sale of our products.

We believe that our cash and cash equivalents and available-for-sale investments as of December 31, 2019, 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:

(in thousands)	Years Ended December 31, 2019	2018
Net cash (used in) provided by:		
Operating activities	$ (29,610)	$ (21,695)
Investing activities	(69,956)	(2,270)
Financing activities	113,757	15,424
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 14,191	$ (8,541)

Net Cash Used in Operating Activities

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, and an increase in the fair value of the convertible preferred stock warrants.

Net cash used in operating activities for the year ended December 31, 2018 was $21.7 million, consisting primarily of a net loss of $37.6 million partially offset by an increase in net operating assets of $0.9 million and non-cash charges of $15.0 million. The increase in net operating assets was primarily due to an increase in accounts receivable, inventories and prepaid expenses and other current assets to support the growth of our operations, partially offset by increases in accrued and other liabilities, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our term loan agreement, and an increase in the fair value of the convertible preferred stock warrants.

Net Cash Used in Investing Activities

Net cash used in investing activities in the 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 used in investing activities in the year ended December 31, 2018 was $2.3 million primarily consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

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.

Net cash provided by financing activities in the year ended December 31, 2018 was $15.4 million primarily attributable to proceeds of $15.0 million from additional borrowings under the term loan agreement, and $0.7 million of proceeds from the exercise of stock options, partially offset by cash paid for deferred initial public offering costs of $0.2 million.

Term Loan Agreement

In October 2015, we entered into the term loan agreement and related security agreement with Capital Resource Group ("CRG"), providing for a term loan facility of up to $30.0 million, available in tranches on the terms and conditions set forth in the term loan agreement. In September 2018, we entered into a fifth amendment to the term loan agreement, or Fifth Amendment, to increase the aggregate term loan commitments from up to $30.0 million to up to $55.0 million, to extend the commitment period from March 29, 2017 to June 30, 2019, to extend the maturity date from September 30, 2021 to December 31, 2022, and to amend certain other terms.

As of December 31, 2019, the aggregate outstanding principal balance (including interest PIK) under the term loan agreement was $44.9 million.

Prior to the Fifth Amendment, the term loans bore interest at a rate of 13.0% per annum, which interest rate was reduced to 10.75% on and after the effective date of the Fifth Amendment, and which interest rate was further reduced to 10.00% on and after the consummation of our initial public offering. We may, at our election, pay the interest through a combination of cash and PIK. The interest is payable in cash and PIK as follows: prior to the Fifth Amendment, 8.50% per annum in cash and 4.50% PIK; on or after the Fifth Amendment, 8.0% per annum in cash and 2.75% PIK; and on and after the consummation of our initial public offering, 8.0% per annum in cash and 2.0% PIK. Interest is due and payable quarterly in arrears. The outstanding principal amount under the term loan agreement, together with all accrued and unpaid interest, is due and payable on December 31, 2022. We may prepay the term loan agreement, in whole or in part, at any time. During 2019 and 2018, we incurred $5.0 million and $4.3 million, respectively, in interest expense in connection with the term loan agreement. During 2019 and 2018, we made cash interest payments of $4.2 million and $2.7 million, respectively, and issued $0.3 million and $1.2 million in PIK interest for the year ended December 31, 2019 and 2018, respectively.

Our obligations under the term loan agreement are guaranteed by our existing and future subsidiaries, subject to exceptions for certain foreign subsidiaries. Our obligations under the term loan agreement are secured by substantially all of our assets, including our material intellectual property, and the assets of our guarantor subsidiaries, subject to certain exceptions. There are currently no guarantor subsidiaries. Additionally, we and our subsidiaries are subject to customary affirmative and negative covenants, including covenants that limit or restrict the ability of us and our subsidiaries to, among other things, incur indebtedness, grant liens, merge or consolidate, make investments, dispose of assets, make acquisitions, pay dividends or make distributions, repurchase stock and enter into certain transactions with affiliates, in each case subject to certain exceptions. We are also required to maintain minimum liquidity that exceeds the greater of $3.0 million or the minimum cash balance required under any permitted accounts receivable credit facility. In addition, we must achieve minimum annual revenue of $40.0 million in 2020. If we fail to satisfy the minimum annual revenue covenant in any measurement period, we can cure the resulting default by raising the revenue shortfall in additional equity or in subordinated debt within 90 days of such calendar year in which the shortfall occurred. As of the date of this Annual Report on Form 10-K, we were in compliance with all covenants under the term loan agreement.

The term loan agreement is subject to customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, cross-defaults to material indebtedness and material agreements, bankruptcy and insolvency defaults, material judgment defaults, ERISA defaults, a change of control default and a material adverse change default. The occurrence of an event of default could result in the acceleration of the obligations under the term loan agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default at a per annum rate equal to 4.0% above the applicable interest rate. On November 14, 2018, we entered into a sixth amendment to the term loan agreement to amend a covenant regarding the timeline for provision of audited financial statements. In June 2019, we entered into a

seventh amendment to the term loan agreement to amend the definition of permitted cash equivalents to reflect updated flexibility.

Cordis License Agreement

In December 2010, we entered into a license agreement, or the Cordis License Agreement, with Cordis Corporation, or Cordis, which is now a subsidiary of Cardinal Health. Pursuant to the Cordis License Agreement, Cordis has 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.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

Our principal obligations consist of the operating lease for our facility, our term loan agreement and non-cancellable inventory purchase commitments. The following table sets out, as of December 31, 2019, our contractual obligations 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	$ 1,006	$ 2,082	$ 1,919	$ —	$ 5,007
Term loan agreement with CRG	4,454	52,698	—	—	57,152
Non-cancellable purchase commitments	3,807	2,260	1,030	—	7,097
	$ 9,267	$ 57,040	$ 2,949	$ —	$ 69,256

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

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

We adopted Accounting Standards Codification, or ASC, Topic 606, "Revenue from Contracts with Customers," using the modified retrospective method applied to contracts which were not completed as of that date effective January 1, 2018. 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, we perform 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.

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.

For sales where the sales representative hand delivers product directly to the hospital or medical center from the sales representative's trunk stock inventory, we recognize revenue upon delivery, which represents the point in time when control transfers to the customer. For sales which are sent directly 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 us or the sales representative to the customer after delivery under either method of sale.

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, which provisions are classified within accrued liabilities on our balance sheet. We have elected to expense shipping and handling costs as incurred and include them within cost of goods sold. In those cases where we invoice shipping and handling costs to customers, we will classify the amounts billed as a component of revenue.

JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have irrevocably elected not to avail ourselves of the exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Issued Accounting Pronouncements

We adopted ASC 842, "Leases," on January 1, 2019 using the modified retrospective method for all leases not substantially completed as of the date of adoption. We elected to apply the package of practical expedients, which allowed us to not reassess: (i) whether expired or existing contracts contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing lease. See Note 3 to our financial statements included elsewhere in this Annual Report on Form 10-K for recently adopted 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, cash equivalents and investments of $108.9 million as of December 31, 2019; which consisted of bank deposits, money market funds, U.S. government securities, corporate bonds/notes, asset-backed securities and commercial paper. The primary objectives of our investment activities are the preservation of capital and support of our liquidity requirements. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our income and the fair market value of our investments.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 10% change in interest rates would not have a material impact on the value of our cash and cash equivalents or our investments as of December 31, 2019.

Credit Risk

As of December 31, 2019 and 2018, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe each to have sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Our cash equivalents and investments are invested in highly rated money market funds, U.S. government securities, corporate bonds/notes, asset-backed securities and commercial paper.

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, 2019 or 2018.

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.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Silk Road Medical, Inc. (the “Company”) as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, of statements of redeemable convertible preferred stock and stockholders’ equity (deficit) and of cash flows for the years then ended, including the related notes and financial statement schedule listed in the index appearing under Item 15 (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements 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 of these financial statements 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 2, 2020

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 39,181	$ 24,990
Short-term investments	51,508	—
Accounts receivable, net of allowances of $45 and $22 at December 31, 2019 and 2018, respectively	8,601	6,382
Inventories	10,322	5,744
Prepaid expenses and other current assets	2,878	1,408
Total current assets	112,490	38,524
Long-term investments	18,224	—
Property and equipment, net	2,734	2,880
Restricted cash	310	310
Other non-current assets	3,644	1,029
Total assets	$ 137,402	$ 42,743
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,898	$ 1,252
Accrued liabilities	15,034	9,448
Total current liabilities	16,932	10,700
Long-term debt	44,879	44,201
Redeemable convertible preferred stock warrant liability	—	16,091
Other liabilities	3,700	1,069
Total liabilities	65,511	72,061
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock issuable in series, $0.001 par value		
Shares authorized: None and 24,069,615 at December 31, 2019 and 2018, respectively		
Shares issued and outstanding: None and 21,233,190 at December 31, 2019 and 2018, respectively		
Liquidation preference: None and $121,144 at December 31, 2019 and 2018, respectively	—	105,235
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 and none at December 31, 2019 and 2018, respectively		
Shares issued and outstanding: None at December 31, 2019 and 2018	—	—
Common stock, $0.001 par value		
Shares authorized: 100,000,000 and 29,879,220 at December 31, 2019 and 2018, respectively		
Shares issued and outstanding: 31,255,267 and 1,135,310 at December 31, 2019 and 2018, respectively	31	1
Additional paid-in capital	263,384	4,557
Accumulated other comprehensive income	2	—
Accumulated deficit	(191,526)	(139,111)
Total stockholders' equity (deficit)	71,891	(134,553)
Total liabilities and stockholders' equity (deficit)	$ 137,402	$ 42,743

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,	
	2019	2018
Revenue	$ 63,354	$ 34,557
Cost of goods sold	15,927	10,874
Gross profit	47,427	23,683
Operating expenses:		
Research and development	12,272	10,258
Selling, general and administrative	63,220	34,820
Total operating expenses	75,492	45,078
Loss from operations	(28,065)	(21,395)
Interest income	1,656	189
Interest expense	(4,952)	(4,361)
Other income (expense), net	(21,054)	(12,063)
Net loss	(52,415)	(37,630)
Net loss attributable to non-controlling interest	—	1
Net loss attributable to Silk Road Medical, Inc. common stockholders	(52,415)	(37,629)
Other comprehensive loss:		
Unrealized gain on investments, net	2	—
Net change in other comprehensive loss	2	—
Net loss and comprehensive loss attributable to Silk Road Medical, Inc. common stockholders	$ (52,413)	$ (37,629)
Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted	$ (2.28)	$ (39.16)
Weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted	22,956,679	960,882

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	Non-controlling Interest	Total
	Shares	Amount	Shares	Amount					
Balances at December 31, 2017	21,233,190	$ 105,235	663,270	$ 1	$ 2,977	$ (101,556)	$ —	$ —	$ (98,578)
Exercise of stock options	—	—	438,578	—	656	—	—	—	656
Employee stock-based compensation	—	—	—	—	728	—	—	—	728
Nonemployee stock-based compensation	—	—	—	—	183	—	—	—	183
NeuroCo common stock issuance	—	—	—	—	—	—	—	1	1
Issuance of common stock in connection with NeuroCo merger	—	—	33,462	—	—	—	—	—	—
Cumulative effect of change in accounting principle - ASC 606 adoption	—	—	—	—	—	87	—	—	87
Cumulative effect of change in accounting treatment - ASU 2016-09	—	—	—	—	13	(13)	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(37,629)	—	(1)	(37,630)
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 $2,481	—	—	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
Employee stock-based compensation	—	—	—	—	2,887	—	—	—	2,887
Nonemployee stock-based compensation	—	—	—	—	90	—	—	—	90
Net loss	—	—	—	—	—	(52,415)	—	—	(52,415)
Unrealized gains on investments, net	—	—	—	—	—	—	2	—	2
Balances at December 31, 2019	—	$ —	31,255,267	$ 31	$ 263,384	$ (191,526)	$ 2	$ —	$ 71,891

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,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (52,415)	$ (37,630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	712	517
Stock-based compensation expense	2,977	911
Change in fair value of redeemable convertible preferred stock warrant liability	21,030	11,906
Accretion of discount on investments	(309)	—
Amortization of debt discount and debt issuance costs	46	68
Amortization of right-of-use asset	582	—
Non-cash interest expense	672	1,555
Loss on disposal of property and equipment	—	159
Provision for doubtful accounts receivable	23	(123)
Provision for excess and obsolete inventories	118	23
Changes in assets and liabilities		
Accounts receivable	(2,241)	(446)
Inventories	(4,696)	(2,565)
Prepaid expenses and other current assets	(1,471)	(1,128)
Other assets	552	(62)
Accounts payable	615	(309)
Accrued liabilities	4,964	5,023
Other liabilities	(769)	406
Net cash used in operating activities	(29,610)	(21,695)
Cash flows from investing activities		
Purchase of property and equipment	(535)	(2,276)
Proceeds from sale of property and equipment	—	6
Purchases of investments	(69,421)	—
Net cash used in investing activities	(69,956)	(2,270)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discount, commissions and offering costs paid	109,352	(233)
Proceeds from long-term debt	—	15,000
Proceeds from issuance of common stock	2,590	656
Proceeds from exercise of redeemable convertible preferred stock warrants	1,784	—
Proceeds from exercise of common stock warrants	31	—
Non-controlling interest	—	1
Net cash provided by financing activities	113,757	15,424
Net change in cash, cash equivalents and restricted cash	14,191	(8,541)
Cash, cash equivalents and restricted cash, beginning of year	25,300	33,841
Cash, cash equivalents and restricted cash, end of year	$ 39,491	$ 25,300
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 4,234	$ 2,738
Non-cash investing and financing activities:		
Accounts payable and accrued liabilities for purchases of property and equipment	$ 32	$ 6
Landlord paid tenant improvements	$ —	$ 794
Unpaid deferred offering costs	$ —	$ 717
Right-of-use asset obtained in exchange for lease obligation	$ 3,982	$ —
Net exercise of redeemable convertible preferred stock warrants to preferred stock	$ 37,121	$ —
Conversion of redeemable 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’s manufactures and sells in the United States its portfolio of TCAR products which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. The Company commercialized its products in the United States in April 2016.

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, 2019, the Company had an accumulated deficit of $191,526,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $39,181,000 and available-for-sale investments of $69,732,000 at December 31, 2019, 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.

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").

Adjustment to Prior Period Financial Statements

The Company has adjusted the accompanying December 31, 2018 balance sheet to increase each of the accounts receivable and accrued liabilities balances by $1,860,000 to correct for an immaterial prior year error in the classification of provisions for returns from customers.

Principles of Consolidation

As of December 31, 2017, the consolidated financial statements of the Company include the accounts of Silk Road Medical, Inc. and its consolidated variable interest entity ("VIE"). Disclosure regarding the Company's participation in the VIE is included in Note 12, "Variable Interest Entity – NeuroCo". On December 17, 2018, the Company acquired all assets and assumed all liabilities of its VIE. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses 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.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2019 and 2018. The carrying amounts of certain of the Company's financial instruments, which include cash equivalents, short-term investments, long-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 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, 2019 and 2018, the Company's cash equivalents are entirely comprised of investments in money market funds.

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

	December 31,	
	2019	2018
Cash and cash equivalents	$ 39,181	$ 24,990
Restricted cash	310	310
Total cash, cash equivalents and restricted cash	$ 39,491	$ 25,300

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

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. 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.

Concentration of Credit Risk, and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, investments and accounts receivable to the extent of the amounts recorded on the balance sheet. Cash, cash equivalents, and investments are deposited in financial institutions which, at times, may be in excess of federally insured limits. Cash equivalents are invested in highly rated money market funds. The Company invests in a variety of financial instruments, such as, but not limited to, commercial paper, corporate bonds/notes, 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, 2019 and 2018.

The Company's accounts receivable are due from a variety of health care organizations in the United States. At December 31, 2019 and 2018, no customer represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2019 and 2018, 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 doubtful 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 stent. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

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

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

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company estimates allowances for doubtful accounts. 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, 2019 and 2018, the Company did not experience any material credit-related losses.

Inventories

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

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation or amortization. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, typically three 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.

Deferred Public Offering Costs

Specific incremental legal, accounting and other fees and costs directly attributable to a proposed or actual offering of securities may properly be deferred and charged against the gross proceeds of the offering. As of December 31, 2018, there were $950,000 of offering costs primarily consisting of legal and accounting fees that were capitalized in other non-current assets on the balance sheet of which $233,000 had been paid. No deferred offering costs were capitalized as of December 31, 2019.

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, 2019 and 2018.

Leases

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

The disclosure impact of the adoption of ASC 842 on the balance sheet was as follows (in thousands):

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

The Company 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's 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, as the Company has elected to account separately for contracts that contain lease and non-lease components, 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 (deficit). 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 (deficit) on the balance sheet as events triggering the liquidation preferences were not solely within the Company's control. Upon the closing of the Company's IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 23,178,555 shares of common stock resulting in the reclassification of $144,140,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

Revenue Recognition

On January 1, 2018, the Company adopted ASC Topic 606, "Revenue from Contracts with Customers," using the modified retrospective method applied to contracts which were not completed as of that date. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

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

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

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

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

Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue earlier for arrangements where the Company has satisfied its performance obligations

but have not issued invoices. As of December 31, 2019 and 2018, the Company recorded $102,000 and $128,000, 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 collectibility is probable. For sales which are sent directly from the Company to hospitals and medical centers, the transfer of control occurs at the time of shipment or delivery of the product. There are no further performance obligations by the Company or the sales representative to the customer after delivery under either method of sale. As allowed under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed.

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

Costs associated with product sales include commissions and royalties. The Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of revenue in the 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 facility and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to

materials, components and subassemblies, manufacturing overhead costs, direct labor, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalties.

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 $362,000 and $186,000 were expensed during the years ended December 31, 2019 and 2018, 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, 2019 and 2018.

Stock–Based Compensation

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") ASC 718, "Compensation-Stock Compensation." ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of all share-based payment option awards on the date of grant using an option pricing model. The fair value of stock options is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a

straight-line basis. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions.

In March 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-09, “Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting.” Under ASU 2016-09, entities are permitted to make an accounting policy election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur. The Company made an accounting policy election to account for forfeitures as they occur. This change has been applied on a modified retrospective basis, resulting in a cumulative-effect adjustment to increase the beginning accumulated deficit by $13,000 as of January 1, 2018, the date of adoption.

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.

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 year ended December 31, 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 (deficit). For the year ended December 31, 2018, there was no difference between the Company's comprehensive loss and its net loss.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is computed by dividing the net loss attributable to common stockholders 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 attributable to common stockholders by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock and warrants, and common stock options are considered to be potentially dilutive securities. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company’s redeemable convertible preferred

stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

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

	Year Ended December 31,	
	2019	2018
Net loss attributable to Silk Road Medical, Inc. common stockholders	$ (52,415)	$ (37,629)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	22,956,679	960,882
Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted	$ (2.28)	$ (39.16)

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,	
	2019	2018
Redeemable convertible preferred stock outstanding	—	21,233,190
Redeemable convertible preferred stock warrants outstanding	—	2,672,502
Common stock options	4,310,790	4,364,377
Common stock warrants outstanding	—	7,527
Total	4,310,790	28,277,596

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. All of the Company's revenue was in the United States for the years ended December 31, 2019 and 2018, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

Recently Adopted Accounting Standards

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

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Statements. This update provides financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The update replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 became effective for the Company on January 1, 2020. The Company does not believe that the adoption of this new guidance will have a material impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement, which changed the disclosure requirements for fair value measurements by removing, adding and modifying certain disclosures. ASU 2018-13 became effective for the Company on January 1, 2020. The Company does not believe that the adoption of this new guidance will have a material impact on its financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, Cloud Computing Arrangements, which aligns the requirements for capitalizing implementation costs in a Cloud Computing Arrangement service contract with the requirements for capitalizing implementation costs incurred for an internal-use software license. ASU 2018-15 became effective for the Company on January 1, 2020. The Company does not believe that the adoption of this new guidance will have a material impact on its financial statements and related disclosures.

In December 2019, the FASB issued 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 intraperiod 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. ASU 2019-12 will become effective for the Company on January 1, 2021. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance to its financial statements and related disclosures.

4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, 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 tables 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, 2019 and 2018, using the inputs defined above (in thousands):

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 34,363	$ —	$ —	$ 34,363
Commercial paper	—	9,919	—	9,919
Corporate bonds/notes	—	10,176	—	10,176
U.S. government securities	—	44,456	—	44,456
Asset-backed securities	—	5,181	—	5,181
	$ 34,363	$ 69,732	$ —	$ 104,095

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 10,495	$ —	$ —	$ 10,495
Liabilities:				
Redeemable convertible warrant liability	$ —	$ —	$ 16,091	$ 16,091

As a derivative liability, the redeemable convertible warrants were initially recorded at fair value and were subject to remeasurement at each 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's redeemable convertible warrant liability was classified within Level 3 of the fair value hierarchy.

At December 31, 2018, the fair value of the redeemable convertible warrant liability was determined by using an option pricing model to allocate the total enterprise value to the various securities within the Company's capital structure. The fair value of the redeemable convertible warrant liability was based on both the estimated fair value of the Company's common stock of $11.29 as of December 31, 2018 and on valuation models discounted at current implied market rates which are based on Level 3 inputs.

Additionally, the model's inputs reflected assumptions that market participants would use in pricing the instrument in a current period transaction and included:

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

The final fair value of the redeemable convertible warrants was remeasured on the date of the Company's initial public offering in April 2019. The final fair value of the redeemable convertible warrant liability was based on the fair value of the Company's common stock at the time of its initial public offering. The following table provides a reconciliation of the beginning and ending balances of the Company's redeemable convertible warrant liability are summarized below (in thousands):

Fair value at December 31, 2017	$ 4,185
Change in fair value recorded in other income (expense), net	11,906
Fair value at December 31, 2018	16,091
Change in fair value recorded in other income (expense), net	21,030
Reclassification upon IPO	(37,121)
Fair Value at December 31, 2019	$ —

There were no transfers between fair value hierarchy levels during the years ended December 31, 2019 and 2018.

5. Balance Sheet Components

Investments

The fair value of the Company's available-for-sale investments as of December 31, 2019 are as follows (in thousands):

	December 31, 2019			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 34,363	$ —	$ —	$ 34,363
Commercial paper	9,919	—	—	9,919
Corporate bonds/notes	10,180	—	(4)	10,176
U.S. government securities	44,450	9	(3)	44,456
Asset-backed securities	5,181	—	—	5,181
	$ 104,093	$ 9	$ (7)	$ 104,095
Classified as:				
Cash equivalents				$ 34,363
Short-term investments				51,508
Long-term investments				18,224
				$ 104,095

The following table summarizes the fair value of the Company’s cash equivalents, short-term and long-term investments classified by maturity as of December 31, 2019 (in thousands):

	December 31, 2019
Amounts maturing within one year	$ 85,871
Amounts maturing after one year through two years	18,224
	$ 104,095

Available-for-sale investments held as of December 31, 2019 had a weighted average days to maturity of 291 days.

The following table presents the Company's available-for-sale investments that were in an unrealized loss position as of December 31, 2019 (in thousands):

	December 31, 2019	
	Less than 12 months	
Assets:	Fair Value	Unrealized Loss
Corporate bonds/notes	$ 10,128	$ (4)
U.S. government securities	19,067	(3)
	$ 29,195	$ (7)

Inventories

Components of inventories were as follows (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 1,203	$ 1,054
Finished products	9,119	4,690
	$ 10,322	$ 5,744

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

Property and Equipment, Net

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

	December 31,	
	2019	2018
Furniture and fixtures	$ 657	$ 517
Equipment	1,295	1,217
Software	18	76
Leasehold improvements	1,991	1,978
	3,961	3,788
Less: Accumulated depreciation and amortization	(1,550)	(946)
Add: Construction-in-progress	323	38
	$ 2,734	$ 2,880

Depreciation and amortization expense was $712,000 and $517,000 for the years ended December 31, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2019	2018
Accrued payroll and related expenses	$ 9,151	$ 5,157
Provision for sales returns	2,419	1,862
Accrued professional services	682	1,014
Operating lease liability	769	—
Accrued royalty expense	470	313
Deferred revenue	304	137
Accrued travel expenses	431	270
Accrued clinical expenses	241	244
Accrued other expenses	567	451
	$ 15,034	$ 9,448

6. Long-term Debt

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

In September 2018, the Company entered into Amendment No. 5 to the term loan agreement with CRG. Under the amended terms of the amended loan agreement the maturity date was extended to December 31, 2022 and the repayment schedule of the existing term loans were changed to interest only so that the outstanding principal amount of the term loans will be payable in a single installment at maturity. The related fixed interest rate was changed to equal 10.75% per annum, due and payable quarterly in arrears. At the election of the Company, 2.75% of the interest due and payable may be “paid in kind” and added to the then outstanding principal and 8.0% of the interest due and payable paid in cash. All unpaid principal, and accrued and unpaid interest, is due and payable in full on December 31, 2022. The amended term loan agreement also provided for additional term loans in an aggregate principal amount of up to $25,000,000 and allowed for the conversion into shares of common stock, at the Company’s option, of up to 25% of the outstanding loans under the term loan agreement in connection with an initial public offering of the Company’s common stock which results in market capitalization of at least $250,000,000. In September 2018, the Company drew down an additional $15,000,000 under the term loan agreement with CRG.

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

The Company may voluntarily prepay the borrowings in full. The Tranche A borrowing required a payment, on the borrowing date, of a financing fee equal to 1.75% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 5.0% of the amounts borrowed plus any “paid in kind” is payable at the end of the term or when the borrowings are repaid in full. A long-term

liability is being accreted using the effective interest method for the facility fee over the term of the loan agreement. The borrowings are collateralized by a security interest in substantially all of the Company's assets.

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

Future maturities under the term loan agreement as of December 31, 2019 are as follows (in thousands):

Year Ending December 31:	**Amount**
2020	$ 4,454
2021	4,442
2022	48,256
	57,152
Add: Accretion of closing fees	1,205
	58,357
Less: Amount representing interest	(13,339)
Less: Amount representing debt discount and debt issuance costs	(139)
Present value of minimum payments	$ 44,879

In October 2015, CRG purchased 327,759 shares of the Company's Series C redeemable convertible preferred stock at $6.11 per share. In addition, CRG received warrants to purchase 163,877 shares of the Company's Series C redeemable convertible preferred stock at an exercise price of $6.11 per share. Upon the closing of the IPO, the warrants were net exercised, based on the IPO price of $20.00 per share, into shares of common stock.

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

7. Commitments and Contingencies

Operating Lease and Rights of Use

The Company's operating lease obligation consists of leased office, laboratory, and manufacturing space under a non-cancellable operating lease that expires in October 2024. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of five years. Operating lease costs were $870,000 for the year ended December 31, 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $721,000 for the year ended December 31, 2019. As of December 31, 2019, the weighted average discount rate was approximately 6.50% and the weighted average remaining lease term was 4.83 years. Balance sheet information as of December 31, 2019 consists of the following (in thousands):

Operating Lease:	**December 31, 2019**
Operating lease right-of-use asset in other non-current assets	$ 3,400
Operating lease liability in accrued liabilities	$ 769
Operating lease liability in other liabilities	3,700
Total operating lease liabilities	$ 4,469

The following table summarizes the Company's operating lease maturities as of December 31, 2019 (in thousands):

Year Ending December 31:	**Amount**
2020	$ 1,037
2021	1,066
2022	1,096
2023	1,127
2024	904
Total lease payments	5,230
Less: imputed interest	(761)
Present value of lease liabilities	$ 4,469

The aggregate future minimum lease payments under ASC 840 as of December 31, 2018 were as follows (in thousands):

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

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. As of December 31, 2019, the Company had non-cancellable purchase obligations to suppliers of $7,097,000.

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, 2019.

Contingencies

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

Legal Matters

In February 2019, a former employee, through counsel, advised the Company that he had filed a charge of discrimination against the Company with the California Department of Fair Employment & Housing, or

DFEH. The former employee's complaint alleged sexual harassment and retaliation in violation of the California Department of Fair Employment & Housing Act. The complaint did not allege specific damages. The Company and the former employee participated in mediation on July 30, 2019 and reached a settlement that required the Company to pay an amount that was not material to its financial statements, which amount was fully paid as of December 31, 2019.

8. Redeemable Convertible Preferred Stock

The Company had the following redeemable convertible preferred stock issued and outstanding at December 31, 2018 (in thousands except share amounts):

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

Upon the closing of the IPO, all shares of redeemable convertible preferred stock then outstanding converted into shares of common stock. As of December 31, 2019, the Company does not have any redeemable convertible preferred stock issued or outstanding.

Redeemable Convertible Preferred Stock Warrants

Upon the closing of the 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, 2019 and 2018, warrants to purchase an aggregate of 0 and 2,672,502, respectively, shares of Series C redeemable convertible preferred stock were outstanding.

9. Stockholders' Equity (Deficit)

Preferred Stock

At December 31, 2019, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At December 31, 2019, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 31,255,267 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, 2019, no dividends have been declared to date. Each share of common stock is entitled to one vote.

At December 31, 2019 and 2018, the Company had reserved common stock for future issuances as follows:

	December 31,	
	2019	2018
Conversion of Series A redeemable convertible preferred stock	—	1,629,629
Conversion of Series A-1 redeemable convertible preferred stock	—	1,111,111
Conversion of Series B redeemable convertible preferred stock	—	6,264,470
Conversion of Series C redeemable convertible preferred stock and warrants	—	15,064,405
Exercise of options under stock plan	4,310,790	4,364,377
Issuance of options under stock plan	1,554,690	57,889
Issuance of common stock under employee stock purchase plan	372,352	—
Warrants to purchase common stock	—	7,527
	6,237,832	28,499,408

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, 2019 and 2018, warrants to purchase an aggregate of 0 and 7,527 shares of common stock were outstanding.

10. Stock Option Plans

In 2007, the Company established its 2007 Stock Option Plan which provided for the granting of stock options to employees, directors and consultants of the Company. In connection with its acquisition of NeuroCo in December 2018, the Company also assumed NeuroCo's 2015 Equity Incentive Plan. In March 2019, the Company's Board of Directors approved the termination of the 2007 Stock Option Plan and the NeuroCo 2015 Equity Incentive Plan and the adoption of the 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the Company's IPO. The 2019 Plan provides for the grant of ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were initially reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan will also include shares reserved but not issued under the 2007 Stock Option Plan, plus any share awards granted under the 2007 Stock Option Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan will also include an annual increase on the first day of each fiscal year beginning in fiscal 2020, equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. As of December 31, 2019, the Company has reserved 2,366,251 shares of common stock for issuance under the 2019 Plan.

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

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

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Balances, December 31, 2017	328,290	4,308,890	$ 3.09	7.81	$ 5,073
Authorized	223,664				
Options granted	(629,716)	629,716	$ 6.51		
Options exercised	—	(438,578)	$ 1.50		
Options cancelled	135,651	(135,651)	$ 1.56		
Balances, December 31, 2018	57,889	4,364,377	$ 3.79	7.36	$ 33,132
Authorized	2,317,000				
Options granted	(848,023)	848,023	$ 22.77		
Options exercised	—	(873,786)	$ 1.77		
Options cancelled	27,824	(27,824)	$ 8.71		
Balances December 31, 2019	1,554,690	4,310,790	$ 7.91	7.27	$ 140,234
Vested and exercisable at December 31, 2019		2,514,891	$ 4.27	6.38	$ 90,854
Vested and expected to vest at December 31, 2019		4,310,790	$ 7.91	7.27	$ 140,234

The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and 2018 was $24,867,000 and $787,000, 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, 2019 and 2018 was $10.17 and $2.93 per share, respectively. The total fair value of options vested during the years ended December 31, 2019 and 2018 was $2,221,000 and $569,000, respectively, based on the grant date fair value.

The following table summarizes information about stock options outstanding and vested as of December 31, 2019:

	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	2,072,765	5.86	$ 1.84	1,770,060	$ 1.71
$4.73 - $8.27	919,355	8.23	$ 5.81	383,077	$ 5.72
$11.29 - $20.00	1,192,804	8.73	$ 16.63	352,383	$ 14.46
$36.47 - $48.53	125,866	9.69	$ 40.50	9,371	$ 45.57
	4,310,790	7.27	$ 7.91	2,514,891	$ 4.27

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 are reserved for issuance and will be increased on the first day of each fiscal year, beginning in 2020, by an amount equal to the lesser of (i) 1,200,000 shares (ii) 1.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2019 ESPP was effective upon adoption by the Company's Board of Directors but was not in use until the completion of the 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, 2019, 61,648 shares of common stock have been issued to employees participating in the 2019 ESPP and 372,352 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, 2019 and 2018:

	Year Ended December 31,	
	2019	**2018**
Expected term (in years)	5.00 - 6.25	5.00 - 6.25
Expected volatility	42.4% - 42.9%	38.0% - 38.8%
Risk-free interest rate	1.47% - 2.54%	2.68% - 2.98%
Dividend yield	—%	—%

Prior to completion of the Company's IPO, 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 examining 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.

Effective January 1, 2018, the Company made an accounting policy election to account for forfeitures 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 year ended December 31, 2019:

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

Total stock-based compensation expense relating to the Company's stock options and 2019 ESPP during the years ended December 31, 2019 and 2018, is as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Cost of goods sold	$ 179	$ 51
Research and development expenses	426	256
Selling, general and administrative expenses	2,372	604
	$ 2,977	$ 911

As of December 31, 2019, there was total unrecognized compensation costs of $8,539,000 related to stock options, which are expected to be recognized over a period of approximately 3.04 years and $219,000 related to the 2019 ESPP, which the Company will recognize over 0.39 years.
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11. Income Taxes

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

	Year Ended December 31,	
	2019	2018
United States	$ (52,415)	$ (37,630)
International	—	—
	$ (52,415)	$ (37,630)

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,	
	2019	2018
Tax at federal statutory rate	$ (11,007)	$ (7,902)
State taxes, net of federal benefit	(2,270)	(1,582)
Permanent differences	(4,731)	289
Loss on Series C warrant liability	5,330	2,500
Change in valuation allowance	12,797	6,197
General business credits	(319)	136
Other	208	376
Provision for income taxes	$ 8	$ 14

The Company's provision for income taxes 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, 2019 and 2018 consist of the following (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 44,574	$ 33,815
Research and development credits	5,287	4,944
Capitalized start-up costs/Intangibles	11	16
Accruals and reserves	2,227	1,169
Property and equipment	188	82
Stock-based compensation	568	274
Operating lease liability	1,133	—
Total deferred tax assets	53,988	40,300
Less: Valuation allowance	(53,126)	(40,300)
Deferred tax liabilities:		
Operating lease asset	(862)	—
Total deferred tax liabilities	(862)	—
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 $12,826,000 during the year ended December 31, 2019 and increased by $6,197,000 during the year ended December 31, 2018.

As of December 31, 2019, the Company had net operating loss carryforwards of approximately $167,948,000 and $148,380,000 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, 2019, the Company had $4,320,000 and $2,860,000 of federal and state research and development credit carryforwards, respectively. 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, 2019, the Company had $1,436,000 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, 2019. 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, 2019 and 2018.

A reconciliation of the unrecognized tax benefits from January 1, 2018 to December 31, 2019 is as follows (in thousands):

	December 31,	
	2019	2018
Balance at the beginning of year	$ 1,348	$ 615
Increases related to current years’ tax positions	88	118
Increases/(decreases) related to prior years’ tax positions	—	615
Balance at end of year	$ 1,436	$ 1,348

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. Acquisition of Variable Interest Entity - NeuroCo

In December 2014, the Board of Directors of the Company approved the sale of certain intellectual property of Silk Road Medical, Inc., to a newly incorporated entity, NeuroCo, Inc. In consideration for the intellectual property, a promissory note was executed between the two parties for the principal sum of $498,000 with an interest rate of 2.74% per annum, payable on the earlier of 10 years from the date of promissory note, or upon the occurrence of an event of default. The intellectual property transfer was recorded at its carrying value of zero as of December 31, 2014. During 2015 NeuroCo issued $154,000 in common stock to stockholders of the Company. During the year ended December 31, 2018, NeuroCo issued common stock upon the exercise of stock options. These common stock issuance amounts, as they are related to non-controlling investors, were reported as non-controlling interests in subsidiary in the Company's financial statements and are offset by NeuroCo losses consolidated by the Company.

Additionally, NeuroCo incurred research and development related expenses paid for by the Company which were added in to the original promissory note.

The Company had identified NeuroCo as a VIE of which the Company is the primary beneficiary. Pursuant to the accounting guidance for consolidating VIEs the main consideration was given to the fact that the amount of total equity investment at risk is not sufficient to permit NeuroCo to finance its activities without additional subordinated financial support. Additionally, NeuroCo and Silk Road Medical had the same Board of Directors and senior management composition, determining the Company to have the power to direct the activities that most significantly impact NeuroCo's economic performance and the obligation to absorb losses and the right to receive benefits. Accordingly, the financial results of NeuroCo were included in the Company's financial statements.

On December 17, 2018, the Company and NeuroCo entered into the Agreement and Plan of Merger (the "Merger Agreement") pursuant to which the Company acquired all assets and assumed all liabilities of NeuroCo (the "Merger"). The Merger closed on the same day (the "Closing") and was consummated through a stock-for-stock transaction based on the relative values of the Company's and NeuroCo's equity. In consideration for 100% equity interest of NeuroCo, the Company issued 33,462 shares of its common stock and the above promissory note in the amount of approximately $1,600,000 as of the Closing was settled and canceled. As a result of the Merger, NeuroCo merged into the Company with the Company being the surviving corporation.

As the Company already controlled and consolidated NeuroCo and retained the control over NeuroCo's business after the Merger, the Company accounted for the acquisition of equity interest in NeuroCo as an equity transaction. Therefore, the Company did not recognize a gain or loss in its net loss or comprehensive loss for acquisition of NeuroCo. As the carrying amount of the non-controlling interest as of the Closing was zero, the Company recorded the consideration paid as a decrease to the Company's additional paid-in capital within stockholder's equity (deficit).

As part of the Merger, the Company assumed NeuroCo's 2015 Equity Incentive Plan (the "NeuroCo Plan") along with all of NeuroCo's rights and obligations under the NeuroCo Plan, except that the number of shares and exercise price of the assumed options have been adjusted based on the Merger exchange ratio of the Company's common stock and NeuroCo's common stock. Similarly, the Company assumed outstanding warrants to purchase NeuroCo's common stock such that the number of shares and exercise price of the assumed warrants have been adjusted based on the Merger exchange ratio of the Company's common stock and NeuroCo's common stock. The options and warrants to purchase shares of the Company's common stock were fully vested upon issuance, as they were replacing fully vested options and warrants to purchase NeuroCo common stock.

13. 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.

14. Subsequent Events

2019 Equity Incentive Plan

In January 2020, the number of shares of common stock authorized for issuance under the 2019 Plan was automatically increased by 1,250,210 shares, which was ratified by the Company's Board of Directors in February 2020.

In February 2020, the Company’s Board of Directors approved the grant of options to purchase 92,885 shares of common stock under the 2019 Plan with an exercise price of $47.20 per share.

2019 Employee Stock Purchase Plan

In January 2020, the number of shares of common stock authorized for issuance under the 2019 ESPP was automatically increased by 312,552 shares, which was ratified by the Company's Board of Directors in February 2020.

15. Quarterly Financial Information (unaudited)

The following table provides selected unaudited quarterly financial data for the years ended December 31, 2019 and 2018 (in thousands, except per share data):

	Three Months Ended			
	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Revenue	$ 18,634	$ 17,026	$ 14,928	$ 12,766
Gross profit	$ 13,913	$ 12,856	$ 11,231	$ 9,427
Net loss	$ (8,291)	$ (8,007)	$ (11,959)	$ (24,158)
Net loss per share, basic and diluted	$ (0.27)	$ (0.26)	$ (0.42)	$ (20.12)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Revenue	$ 11,470	$ 9,614	$ 7,767	$ 5,706
Gross profit	$ 7,803	$ 6,732	$ 5,376	$ 3,772
Net loss	$ (15,618)	$ (8,953)	$ (7,651)	$ (5,408)
Net loss per share, basic and diluted	$ (14.12)	$ (8.49)	$ (8.16)	$ (7.31)

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

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to provide reasonable assurance 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 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 the 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. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2019, the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective because of the material weaknesses described below.

Material Weaknesses in Internal Control Over Financial Reporting

In connection with our preparation for our initial public offering, we identified two material weaknesses in our internal control over financial reporting for the year ended December 31, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The first material weakness identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements. The second material weakness was that we did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations resulting in inappropriate segregation of duties over manual journal entries. These material weaknesses resulted in audit adjustments to the Company's financial statements for the years ended December 31, 2017, 2018 and 2019, which did not result in a restatement to the Company’s annual or interim financial statements. Additionally, these material weaknesses could result in misstatements of the account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Remediation Plan and Other Information

With the oversight of senior management and our audit committee, we executed the implementation of remediation steps in 2018. These efforts focused on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. While we believe the measures described above will remediate the material weaknesses identified and strengthen our internal control over financial reporting, both the implemented and enhanced controls have not operated for a sufficient period of time to demonstrate that the material weaknesses are fully

remediated. As such, the remediation initiatives outlined above were not sufficient to fully remediate the material weaknesses in internal control over financial reporting for the year ended December 31, 2019. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

Changes in Internal Control over Financial Reporting

As described under the Remediation Plan and Other Information section above, we enhanced controls related to our journal entry process during the quarter ended December 31, 2019. There were no other changes in our internal control over financial reporting that occurred during the most recent fiscal quarter covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers and Directors

The following table sets forth information, as of February 28, 2020, regarding our executive officers and directors.

Name	Age	Title
Executive Officers		
Erica J. Rogers	56	President, Chief Executive Officer and Director
Lucas W. Buchanan	42	Chief Financial Officer
Andrew S. Davis	51	Executive Vice President of Global Sales and Marketing
Richard M. Ruedy	53	Executive Vice President of Regulatory Affairs, Clinical Affairs and Quality Assurance
Non-Employee Directors		
Ruoxi Chen[1][2]	36	Director
Tony M. Chou, M.D.	59	Director
Amr Kronfol	39	Director
Jack W. Lasersohn[2]	66	Director
Robert E. Mittendorff, M.D.[2]	43	Director
Elizabeth H. Weatherman[1]	60	Director
Donald J. Zurbay[1]	52	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.

Executive Officers

Erica J. Rogers. Ms. Rogers has served as our President and Chief Executive Officer and a member of our board of directors since October 2012. Ms. Rogers previously served as Chief Operating Officer of Medicines360, a non-profit pharmaceutical company developing drugs and devices for women from June 2010 to October 2012. Ms. Rogers was an Executive Vice President at Nanosys, Inc. from December 2008 to March 2010. Prior to that, Ms. Rogers founded and was Chief Executive Officer of Allux Medical, and co-founded Visiogen, which was acquired by Abbott Medical Optics in 2009. She worked previously in neurovascular marketing at Target Therapeutics and peripheral vascular sales and sales training at Boston Scientific. Ms. Rogers received a B.S. in zoology from San Diego State University.

We believe Ms. Rogers' management experience in the medical device industry, her experience in founding and building medical device companies and her extensive understanding of our business, operations, and strategy qualify her to serve on our board of directors.

***Lucas W. Buchanan*.** Mr. Buchanan has served as our Chief Financial Officer since July 2016 and since August 2009 has held multiple roles including Executive Vice President, Commercialization and Corporate Development and Vice President, Marketing and Business Development. From May 2013 to May 2014, Mr. Buchanan was a Senior Director of Strategy and Corporate Development at Impax Laboratories. From 2009 to 2011, Mr. Buchanan was part of our early team while employed at The Vertical Group, a venture capital firm and the founder of our company. He previously worked at Medtronic and at Ernst & Young Corporate Finance LLC. Mr. Buchanan received a B.A. in economics from Duke University and an M.B.A. in health care management from The Wharton School at the University of Pennsylvania.

Andrew S. Davis. Mr. Davis joined us in May 2015 as our Executive Vice President of Global Sales and Marketing. From September 2014 to May 2015, Mr. Davis was Vice President of Sales and Marketing for U.S. and Canada in the Advanced Wound Therapy Group of Acelity. Mr. Davis previously held various leadership positions at Medtronic from 1999 until September 2014, where he most recently served as U.S. Vice President of Sales for CoreValve catheter-based therapies and prior to that U.S. Vice President of Sales for Endovascular. Prior to Medtronic, Mr. Davis worked in sales at Boston Scientific. Mr. Davis received a B.S. in political science from Florida State University.

***Richard M. Ruedy*.** Mr. Ruedy joined us in 2011 and is the Executive Vice President of Clinical and Regulatory Affairs, and Quality Assurance. Mr. Ruedy was previously Vice President of Regulatory, Clinical and Quality for Nevro Corporation from 2009 to 2010 Prior to Nevro, Mr. Ruedy served as Vice President of Regulatory Clinical and Quality affairs of Cardica Inc. from April 2007 to May 2009. Mr. Ruedy also previously served as Director of Regulatory Affairs at Abbott Vascular, co-founded Acta Vascular (acquired by Covidien) and previously held positions of increasing responsibility at Edwards Lifesciense, Medtronic, TriPath Imaging (acquired by Becton Dickinson), and Parallax Medical (acquired by Arthrocare). Mr. Ruedy received a B.A. in English and international relations from Bucknell University.

Non-Employee Directors

Ruoxi Chen. Mr. Chen has served as a member of our board of directors since August 2016. Since August 2011 Mr. Chen has been employed at Warburg Pincus, where he is currently a Principal, focusing on healthcare and consumer investments. Mr. Chen previously worked as an Associate at The Carlyle Group from 2007 to 2009 and in investment banking at Citigroup Global Markets from 2005 to 2007. Mr. Chen received a B.S. in economics and computer science from Duke University and an M.B.A. from Harvard Business School.

We believe Mr. Chen is qualified to serve on our board of directors due to his extensive experience as a private equity investor in healthcare and medical device companies.

***Tony M. Chou, M.D*.** Dr. Chou has served as a member of our board of directors since March 2007. Dr. Chou has been a general partner at The Vertical Group, a healthcare-focused venture capital firm, since August 2006. After joining The Vertical Group, Dr. Chou co-founded our company in 2007 and served as Chief Executive Officer until November 2010. Prior to that, Dr. Chou had general management and business development responsibilities in the Abbott Vascular Division of Abbott Laboratories and last served as Division Vice President and General Manager of vascular closure, managing the FDA approval and global launch of the Perclose and Starclose products. Dr. Chou was previously the Director of the Adult Cardiac Catheterization Laboratory at the University of California, San Francisco, where he is currently Associate Professor of Medicine. Dr. Chou received a B.S. in physics and electrical engineering from Carnegie Mellon University and an M.D. from Case Western Reserve University.

We believe Dr. Chou is qualified to serve on our board of directors due to his role as a co-founder of our company, background as a practicing physician and professor of medicine, experience in the medical device industry and extensive knowledge of our business.

Amr Kronfol. Mr. Kronfol has served on our board of directors since March 2019. Mr. Kronfol has been employed at Warburg Pincus since 2009, where he has been a Managing Director since 2018, focusing on investment activities in the healthcare, technology and consumer/retail industries. He previously worked at Merrill Lynch, where he was a Vice President in the fixed income division and at Tigris Consulting. Mr. Kronfol serves on the boards of a number of private medical and technology companies. Mr. Kronfol received an A.B. in computer science from Princeton University and an M.B.A. from The Wharton School at the University of Pennsylvania.

We believe that Mr. Kronfol is qualified to serve on our board of directors due to his extensive experience as a private equity investor and as a director of companies in the medical device industry.

Jack W. Lasersohn, J.D. Mr. Lasersohn has served as a member of our Board since April 2007. Since 1988, Mr. Lasersohn has been a general partner, or a principal of the general partner, of The Vertical Group, L.P., a private venture capital firm that is focused on the fields of medical technology and biotechnology. The Vertical Group was a co-founder of our company. Prior to joining The Vertical Group's predecessor, F. Eberstadt, in 1981, Mr. Lasersohn was a corporate attorney with Cravath, Swaine & Moore LLP. Mr. Lasersohn served on the board of directors of Masimo Corporation, a publicly traded global medical technology company, from January 1995 to 2017 and has served on the board of directors of OncoMed Pharmaceuticals, Inc., a publicly traded clinical development-stage biopharmaceutical company, since July 2005. He also serves on the boards of a number of private medical device and biotechnology companies. Mr. Lasersohn is the past Chairman of the Medical Industry Group of the National Venture Capital Association, or NVCA, and previously served on the Executive Committee of the board of directors of the NVCA. Mr. Lasersohn has also served, by appointment, on various committees advising the U.S. Food and Drug Administration and the Center for Medicare and Medicaid Services. He holds a B.S. in physics from Tufts University, an M.A. from The Fletcher School of Law and Diplomacy, and a J.D. from Yale Law School.

We believe Mr. Lasersohn is qualified to serve on our board of directors due to his extensive experience as a venture capital investor and as a member of the boards of directors of multiple public and private medical device and biotechnology companies.

Robert E. Mittendorff, M.D. Dr. Mittendorff has served on our board of directors since July 2017. Dr. Mittendorff has been a partner at Norwest Venture Partners since February 2012. Dr. Mittendorff was previously the VP of Marketing and Business Development at Hansen Medical, Inc. Dr. Mittendorff currently serves on the board of directors of several private companies and is also a board certified emergency physician. Dr. Mittendorff received a B.S. in biomedical engineering from Johns Hopkins University, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School.

We believe Dr. Mittendorff is qualified to serve on our board of directors due to his background as a practicing physician, extensive experience as an investor and his role as a board member of several medical device companies.

Elizabeth H. Weatherman. Ms. Weatherman has served on our board of directors since April 2013. Ms. Weatherman has been a Special Limited Partner of Warburg Pincus since January 2016. Ms. Weatherman previously was a Managing Director of Warburg Pincus and a member of the firm's Executive Management Group. Ms. Weatherman joined Warburg Pincus in 1988 and led the firm's Healthcare Group from 2008 to 2015. Ms. Weatherman serves on the board of directors of Wright Medical Group, N.V., Vapotherm Inc., and Nevro Corp., all publicly traded medical device companies. She serves on the Advisory Council of the Stanford Graduate School of Business, and on the board of trustees of Mount Holyoke College and Saint Ann's School in Brooklyn, NY. Ms. Weatherman received a B.A. from Mount Holyoke College and an M.B.A. from the Stanford Graduate School of Business.

We believe that Ms. Weatherman is qualified to serve on our board of directors due to her extensive experience as a private equity investor and a director of public companies in the medical device industry.

Donald J. Zurbay. Mr. Zurbay has served on our board of directors since March 2018. Mr. Zurbay has been Chief Financial Officer of Patterson Companies, Inc., a publicly traded global medical device company, since June 2018. From March 2004 to February 2017, Mr. Zurbay held various leadership positions at St. Jude Medical, Inc., where he most recently served as Vice President and Chief Financial Officer from August 2012 to January 2017. Mr. Zurbay previously worked at PricewaterhouseCoopers as an Assurance and Business Advisory Services Senior Manager. Prior to PricewaterhouseCoopers, he was a General Accounting Manager at The Valspar Corporation. Prior to The Valspar Corporation, Mr. Zurbay was an auditor at Deloitte & Touche. Mr. Zurbay is a member of the American Institute of Certified Accountants and the Minnesota Society of Certified Public Accountants. Mr. Zurbay received a B.S. in business with an emphasis in accounting from the University of Minnesota.

We believe that Mr. Zurbay is qualified to serve on our board of directors due to his current and prior experience at leading publicly traded healthcare companies, including as a Chief Financial Officer, and his financial experience and expertise.

Executive Officers

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

Board of Directors

Our business is managed under the direction of our board of directors, which currently consists of eight directors. Our directors hold office until the earlier of their death, resignation, removal or disqualification, or until their successors have been elected and qualified. We do not have a chair of our board of directors. Our board of directors does not have a formal policy on whether the roles of chief executive officer and chair of our board of directors should be separate. The members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation and a stockholders agreement among certain of our stockholders, and, under the terms of such stockholders agreement, the stockholders who are party to the stockholders agreement have agreed to vote their respective shares to elect: (1) one director who is our then-current Chief Executive Officer, currently Erica J. Rogers; (2) two directors designated by the holders of the Series A preferred stock, currently Dr. Tony M. Chou and Jack W. Lasersohn; (3) three directors designated by the holders of the Series B preferred stock, currently Amr Kronfol, Ruoxi Chen, and Donald Zurbay; and (4) two directors designated by the holders of the Series C preferred stock (one of whom shall be designated by Norwest subject to their ownership of at least 50% of the shares of Series C preferred stock purchased by them pursuant to the Series C Preferred Stock Purchase Agreement), currently Dr. Robert E. Mittendorff and Elizabeth H. Weatherman. Dr. Chou and Mr. Lasersohn were designated and appointed as directors by the Vertical Group; Messrs. Chen, Kronfol and Zurbay and Ms. Weatherman were appointed as directors by Warburg; and Dr. Mittendorff was appointed as a director by Norwest.

For as long as Warburg owns at least ten percent (10%) of our issued and outstanding common stock, we will nominate and use commercially reasonable efforts (including, without limitation, soliciting proxies for each designee of Warburg to the same extent we do so for any of its other nominees to the board of directors) to have such number of individuals designated by Warburg elected to the board of directors so that the number of individuals designated by Warburg for election to the board of directors as compared to the size of the board of directors is proportionate to the number of shares of issued and outstanding common stock then owned by Warburg as compared to the number of shares of issued and outstanding common stock at such time; provided, however, that as long as Warburg owns at least ten percent (10%) of the issued and outstanding common stock, Warburg has the right to designate at least one (1) individual for election to our board of directors.

Our board of directors was divided into three classes with staggered three-year terms. Our first annual meeting of stockholders will be in 2020. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Our directors are divided among the three classes as follows:

- Class I directors are Ms. Rogers and Messrs. Kronfol and Lasersohn, and their terms will expire at our annual meeting of stockholders to be held in 2020;
- Class II directors are Dr. Mittendorff, Dr. Chou and Mr. Chen, and their terms will expire at our annual meeting of stockholders to be held in 2021; and
- Class III directors are Mr. Zurbay and Ms. Weatherman, and their terms will expire at our annual meeting of stockholders to be held in 2022.

This classification of the board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management. See “Description of Capital Stock—Anti-Takeover Effects or Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law” for a discussion of other anti-takeover provisions that are included in our amended and restated certificate of incorporation.

Director Independence

Our common stock is quoted on The Nasdaq Stock Market. Under the rules of The Nasdaq Stock Market, independent directors must comprise a majority of a listed company’s board of directors within a specified period of time after listing on The Nasdaq Stock Market. Under Nasdaq Listing Rule 5605(a)(2), a director will qualify as an “independent director” only if, in the opinion of the company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has reviewed the independence of each director and determined that Dr. Chou, Mr. Lasersohn, Dr. Mittendorff, Ms. Weatherman and Mr. Zurbay, representing five of our eight directors, are independent directors under the rules of The Nasdaq Stock Market. Our board of directors will review the independence of each director at least annually. During these reviews, the board of directors will consider transactions and relationships between each director, and his or her immediate family and affiliates, and our company and its management to determine whether any such transactions or relationships are inconsistent with a determination that the director is independent. This review will be based primarily on responses of the directors to questions in a directors’ and officers’ questionnaire regarding employment, business, familial, compensation and other relationships with our company including its management.

In addition, the rules of The Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company’s audit, compensation, and nominating and governance committees be independent. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. Members of the compensation committee must also satisfy additional independence requirements set forth in Nasdaq Listing Rule 5605(d)(2). In order to be considered independent for purposes of Nasdaq Listing Rule 5605(d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member of the compensation committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries. Additionally, the board of directors of the listed company must consider whether the compensation committee member is an affiliated person of the listed company or any of its subsidiaries and, if so, must determine whether such affiliation would impair the director’s judgment as a member of the compensation committee.

We believe that a majority of our directors and the composition of our board of directors meets the requirements for independence under the current requirements of the SEC and The Nasdaq Stock Market. As required by The Nasdaq Stock Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

Corporate Governance

We believe that good corporate governance is important to ensure that, as a public company, we will be managed for the long-term benefit of our stockholders. We and our board of directors have been reviewing the corporate governance policies and practices of other public companies, as well as those

suggested by various authorities in corporate governance. We have also considered the provisions of the Sarbanes-Oxley Act and the rules of the SEC and The Nasdaq Stock Market.

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, our board of directors has approved charters for the audit committee, compensation committee and nominating and corporate governance committee, as well as a code of business conduct and ethics applicable to all of our directors, officers and employees.

Board Committees

Our board of directors has established a standing audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors has assessed the independence of the members of each of these standing committees as defined under the rules of The Nasdaq Stock Market and, in the case of the audit committee, the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or Exchange Act.

Audit Committee

Ms. Weatherman and Messrs. Chen and Zurbay serve on our audit committee. Mr. Zurbay serves as the chair of the audit committee. Our board of directors has determined that Ms. Weatherman and Mr. Zurbay meet the independence and experience requirements applicable to audit committee members under the rules of The Nasdaq Stock Market and the SEC and that Mr. Zurbay is an “audit committee financial expert” as defined under applicable rules of the SEC. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of The Nasdaq Stock Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Ms. Weatherman and Messrs. Chen and Zurbay have met the financial literacy and financial sophistication requirements under SEC and The Nasdaq Stock Market rules. Mr. Chen is currently not considered to be an independent audit committee member within the meaning of applicable SEC and Nasdaq rules, but our board has determined to keep him on the audit committee based on his qualifications and experience. As a result, Mr. Chen does not fall under the safe harbor provision of Rule 10A-3 of the Exchange Act and is not considered independent under such rule. Until we locate a suitable replacement for Mr. Chen, we plan to rely on SEC and Nasdaq rules for phasing in new independent audit committee members. The audit committee’s primary responsibilities include:

- Appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is PricewaterhouseCoopers LLP;
- Reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- Preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- Monitoring our internal control over financial reporting, disclosure controls and procedures;
- Reviewing our risk management status;
- Establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- Meeting independently with our independent registered public accounting firm and management; and
- Monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our board of directors has adopted a written charter for the audit committee, which is available on our website.

Compensation Committee

Dr. Mittendorff and Messrs. Chen and Lasersohn serve on our compensation committee. Mr. Lasersohn serves as the chair of the compensation committee. Dr. Mittendorff and Mr. Lasersohn meet the independence requirements of Nasdaq Rule 5605(d)(2). Mr. Chen is not currently considered to be independent and our board has determined to keep Mr. Chen on the compensation committee in reliance on Nasdaq Rule 5605(d)(2)(B). The compensation committee's responsibilities include:

- Annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- Annually reviewing and making recommendations to our board of directors with respect to the compensation of our chief executive officer and determining the compensation for our other executive officers;
- Reviewing and making recommendations to our board of directors with respect to director compensation; and
- Overseeing and administering our equity incentive plans.

Our chief executive officer and our vice president of human resources make compensation recommendations for our other executive officers and initially proposes the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee. From time to time, our compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, we have periodically engaged Compensia, Inc., to help develop our compensation philosophy, select of a group of peer companies to use for compensation benchmarking purposes and cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our board of directors has adopted a written charter for the compensation committee, which is available on our website.

Nominating and Corporate Governance Committee

Ms. Weatherman and Messrs. Lasersohn and Zurbay serve on our nominating and corporate governance committee. Ms. Weatherman serves as the chair of the nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing, updating and recommending to our board of directors corporate governance principles and policies; and
- overseeing the evaluation of our board of directors and committees.

We expect our nominating and corporate governance committee to adopt a written charter that satisfies the applicable listing standards of The NASDAQ Stock Market. Once adopted, a copy of the charter of our nominating and corporate governance committee will be available on our website.

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.silkroadmed.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this Annual Report on Form 10-K does not incorporate by reference into this Annual Report on Form 10-K the information on or accessible through our website.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- Any breach of the director's duty of loyalty to us or our stockholders;
- Any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- Unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- Any transaction from which the director derived an improper personal benefit.

Our board of directors has adopted an amended and restated certificate of incorporation and amended and restated bylaws, and it provides that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provides that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permits us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

Item 11. Executive Compensation

Summary Compensation Table

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by our principal executive officer and our two other most highly compensated executive officers who were serving as executive officers during the years ended December 31, 2019 and 2018. These individuals were our named executive officers for 2019 and 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Awards ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Erica J. Rogers	2019	$ 421,167	$ 64,500	$ —	$ 2,734,154	$ 459,240	$ —	$ 4,850	$ 3,683,911
President, Chief Executive Officer and Director	2018	390,000	234,000	—	—	—	—	—	624,000
Lucas W. Buchanan	2019	365,583	46,250	—	635,071	329,300	—	14,646	1,390,850
Chief Financial Officer	2018	350,000	210,000	—	—		—	—	560,000
Andrew S. Davis	2019	430,583	54,375	—	334,249	387,150	—	11,817	1,218,174
Executive Vice President, Global Sales and Marketing	2018	415,000	199,000	—	12,067	—	—	—	626,067

(1) Amounts for 2018 reflect a year-end discretionary bonus paid on February 15, 2019. Amounts for 2019 reflect a year-end discretionary bonus paid on February 28, 2020.
(2) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officers calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Common Stock Valuation and Stock-Based Compensation."
(3) Non-Equity Incentive Plan Compensation amounts for 2019 for all named executive officers were paid on February 28, 2020, pursuant to our 2019 Bonus Plan, as described in the section below titled "Executive Compensation—Non-Equity Incentive Plan Compensation."

Narrative Disclosure to Summary Compensation Table

Non-Equity Incentive Plan Compensation

We provide each of our named executive officers an opportunity to receive formula-based incentive payments. The payments are based on a target incentive amount for each named executive officer. In addition, based on exceptional performance of each of our named executive officers during 2019, our board of directors determined to provide each named executive officer an additional discretionary bonus that was in excess of the amount determined under our 2019 Bonus Plan.

Non-Equity Incentive Payments for 2019

For 2019, the target incentive amount and year-end payments for Erica J. Rogers, Lucas W. Buchanan and Andrew S. Davis under our 2019 Bonus Plan were as follows:

Named Executive Officer	Target Award ($)	Actual Award Amount Based on Corporate Performance ($)
Erica J. Rogers	$ 258,000	$ 459,240
Lucas W. Buchanan	185,000	329,300
Andrew S. Davis	217,500	387,150

The 2019 Bonus Plan provided for non-equity incentive compensation based upon our achievement of performance goals for 2019 at 178% of target. The actual target incentive payments were weighted 100% toward achievement of Company goals which included achieving revenue and clinical outcome targets.

Outstanding Equity Awards at 2019 Year-End

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2019:

	Option Awards						Stock Awards	
Name	Grant Date[1]	Vesting Commencement Date[2]	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[3]	Option Expiration Date	Number of Shares or Units of Stock That Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Erica J. Rogers	12/14/2012	10/23/2012	81,510	—	$ 1.38	12/14/2022	—	—
	12/14/2012	10/23/2012	82,512	—	$ 1.38	12/14/2022	—	—
	12/24/2014	12/24/2014	61,728	—	$ 1.46	12/24/2024	—	—
	12/3/2015	12/3/2015	143,290	—	$ 1.60	12/13/2025	—	—
	8/4/2016	8/4/2016	216,049	43,210	$ 1.60	8/4/2026	—	—
	9/30/2016	9/30/2016	330	—	$ 8.27	9/30/2026	—	—
	11/30/2017	8/1/2017	43,209	30,865	$ 6.11	11/30/2027	—	—
	11/30/2017	8/1/2017	213,888	152,778	$ 12.15	11/30/2027	—	—
	11/30/2017	8/1/2017	—	22,222	$ 12.15	11/30/2027	—	—
	4/3/2019	4/3/2019	50,493	252,469	$ 20.00	4/3/2029	—	—
Lucas W. Buchanan	12/24/2014	12/24/2014	7,408	—	$ 1.46	12/24/2024	—	—
	12/3/2015	12/3/2015	207,795	—	$ 1.60	12/3/2025	—	—
	8/4/2016	8/4/2016	41,666	8,334	$ 1.60	8/4/2026	—	—
	9/30/2016	9/30/2016	398	—	$ 8.27	9/30/2026	—	—
	11/30/2017	8/1/2017	42,630	35,899	$ 4.73	11/30/2027	—	—
	11/30/2017	8/1/2017	19,652	14,037	$ 12.15	11/30/2027	—	—
	11/30/2017	8/1/2017	—	25,847	$ 12.15	11/30/2027	—	—
	4/3/2019	4/3/2019	11,728	58,642	$ 20.00	4/3/2029	—	—
Andrew S. Davis	6/23/2015	5/5/2015	125,623	—	$ 1.46	6/23/2025	—	—
	12/3/2015	12/3/2015	45,780	—	$ 1.60	12/3/2025	—	—
	11/30/2017	8/1/2017	—	36,111	$ 4.73	11/30/2027	—	—
	11/30/2017	8/1/2017	49,150	35,109	$ 4.73	11/30/2027	—	—
	9/13/2018	8/1/2018	987	1,975	$ 6.11	9/13/2028	—	—
	4/3/2019	4/3/2019	6,172	30,865	$ 20.00	4/3/2029	—	—

(1) Each of the outstanding stock options was granted pursuant to our 2007 Stock Plan or 2019 Equity Incentive Plan.

(2) Options generally vest over four years from the vesting commencement date in 48 equal monthly amounts, subject to continued service through each such vesting date, provided that the option grants to (x) Ms. Rogers on November 30, 2017 for 74,074 and 388,888 shares, respectively, (y) Mr. Buchanan on November 30, 2017, for 86,157 and 59,536 shares, respectively, and (z) Mr. Davis on November 30, 2017, for 120,370 shares will accelerate and fully vest if the applicable optionee experiences an involuntary termination under certain circumstances within the 12 month period following a change in control of the Company. The option grants to (i) Ms. Rogers on November 30, 2017, for 22,222 shares, (ii) Mr. Buchanan on November 30, 2017, for 25,847 shares and (iii) Mr. Davis on November 30, 2017, for 36,111 shares all vest upon the earlier of a change in control of the Company or the two year anniversary of the initial public offering of the Company's common stock, provided that each such option will accelerate and fully vest upon the involuntary termination of the applicable optionee under certain circumstances. The option grant to Mr. Buchanan on December 3, 2015 for 226,995 shares vested 85,122 shares on the vesting commencement date and the remaining shares vested over thirty months from the vesting commencement date in equal monthly amounts. The option grants to Mr. Davis on June 23, 2015 and September 13, 2018 for 138,893 shares and 2,962 shares, respectively, vest over four years from the vesting commencement date, with 25% vested on the one year anniversary of the vesting commencement date, and with the remaining amount vesting monthly over the subsequent 36 months in equal amounts.

(3) This column represents the fair market value of our common stock on the date of grant, as determined by our board of directors.

Pension Benefits and Nonqualified Deferred Compensation

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2019.

Executive Officer Confirmatory Employment Letters

In March 2019, we entered into confirmatory employment letters with each of our named executive officers. Each letter has no specific term and provides for at-will employment. Each letter also provides that for our 2019 fiscal year, the applicable employee will have the opportunity to earn a target annual cash bonus based on achieving performance objectives established by our board of directors or compensation committee equal to a percentage of the employee's annual base salary, with such percentage being 60% for Ms. Rogers, 50% for Mr. Buchanan, and 50% for Mr. Davis, respectively. Each letter also provides for an annual base salary, with such salary being $430,000 for Ms. Rogers, $370,000 for Mr. Buchanan, and $435,000 for Mr. Davis.

Executive Officer Change in Control and Severance Agreements

In March 2019, we entered into change of control and severance agreements with each of our named executive officers, which superseded all previous severance and change of control arrangements we had entered into with these employees. Each of these agreements has a term of three years. Under each of these agreements, if, within the period three months prior to and 12 months following a "change of control" (such period, the change in control period), we terminate the employment of the applicable employee without "cause" (excluding by reason of the employee's death or "disability,") or the employee resigns for "good reason" (as such terms are defined in the employee's change of control and severance agreement) and the employee executes a separation agreement and release of claims that becomes effective and irrevocable within 60 days following the employee's termination, the employee is entitled to receive (i) a lump sum severance payment, less applicable withholdings, equal to the payment of employee's base salary, as then in effect, of 18 months for Ms. Rogers, 12 months for Mr. Buchanan, and six months for Mr. Davis, respectively, plus, for Ms. Rogers and Mr. Davis, one additional month for each year the applicable employee has remained our employee through the termination date (with partial years of employment rounded up to a whole year), up to a limit of 24 months for Ms. Rogers and 12 months for Mr. Davis, respectively (such monthly period, the severance period) (ii) a lump sum payment, less applicable withholdings, equal to a percentage of the employee's annual target bonus for the year in which the termination occurs, with such percentage being 100% for Ms. Rogers and Mr. Buchanan and 50% for Mr. Davis, respectively, plus, for Ms. Rogers and Mr. Davis, 8.33% for each full year the applicable employee has remained our employee through the termination date (with partial years of employment rounded up to a whole year), up to a limit of 200% for Ms. Rogers and 100% for Mr. Davis, respectively, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for the employee and the employee's dependents through the applicable employee's severance period (with an additional limit of 18 months for Ms. Rogers), and (iv) accelerated vesting as to 100% of the employee's outstanding unvested equity awards.

In addition, under each of these agreements, if, outside of the change in control period, we terminate the employment of the applicable employee without cause (excluding by reason of the employee's death or disability), or the employee resigns for good reason, and the employee executes a separation agreement and release of claims that becomes effective and irrevocable within 60 days following the employee's termination, the employee is entitled to receive (i) a lump sum severance payment, less applicable withholdings, equal to the payment of, for Ms. Rogers and Mr. Buchanan, the employee's base salary, as then in effect, for 12 months for Ms. Rogers, nine months for Mr. Buchanan, respectively, and for Mr. Davis, six months of Mr. Davis' average total annualized cash compensation, as measured over the prior 12 month period preceding Mr. Davis' termination of employment, including salary, commissions and bonuses, and (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for the employee and the employee's dependents for 12 months for Ms. Rogers, nine months for Mr. Buchanan, and six months for Mr. Davis, respectively.

Under each of these agreements, in the event any payment to the applicable employee pursuant to his or her change of control and severance agreement would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, or the Code (as a result of a payment being classified as a parachute payment under Section 280G of the Code), the employee will receive such payment as would entitle the employee to receive the greatest after-tax benefit, even if it means that we pay him or her a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

Employee Benefit and Stock Plans

2019 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, our 2019 Equity Incentive Plan, or the 2019 Plan. Our 2019 Plan became effective upon the completion of our initial public offering in April 2019. Our 2019 Plan permits the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

Authorized Shares. A total of 2,317,000 shares of our common stock are reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under our 2019 Plan will also include shares reserved but not issued under the 2007 Stock Plan, as amended, or the 2007 Plan, and shares subject to stock options or similar awards granted under the 2007 Plan that expire or terminate without having been exercised in full and shares issued pursuant to awards granted under the 2007 Plan that are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2019 Plan pursuant to this sentence is 4,170,676 shares). In addition, shares may become available under the 2019 Plan as described below.

The number of shares available for issuance under the 2019 Plan includes an annual increase on the first day of each fiscal year beginning in fiscal 2019, equal to the lesser of:

- 3,000,000 shares;
- 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under our 2019 Plan.

With respect to stock appreciation rights, the net shares issued will cease to be available under the 2019 Plan and all remaining shares will remain available for future grant or sale under the 2019 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under our 2019 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under our 2019 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2019 Plan. In addition, if we determine it is desirable to qualify transactions under the 2019 Plan as exempt under Rule 16b-3 of the Exchange Act, or Rule 16b-3, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of

our 2019 Plan, the administrator will have the power to administer our 2019 Plan and make all determinations deemed necessary or advisable for administering the 2019 Plan, such as the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2019 Plan, determine the terms and conditions of awards (such as the exercise price, the times or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2019 Plan and awards granted under it, to prescribe, amend, and rescind rules relating to our 2019 Plan, including creating sub-plans, and to modify or amend each award, such as the discretionary authority to extent the post-termination exercisability period of awards (provided that no option or stock appreciation right will be extended past its original maximum term, and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also will have the authority to institute an exchange program by which (i) outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, (ii) participants have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions will be final and binding on all participants.

Stock Options. Stock options may be granted under our 2019 Plan. The exercise price of options granted under our 2019 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2019 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2019 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2019 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2019 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2019 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions for lapse of the restriction on the shares it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided,

however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to the restriction, unless the administrator provides otherwise. Shares of restricted stock as to which the restrictions have not lapsed are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2019 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2019 Plan, the administrator will determine the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restricted stock units will vest.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2019 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance criteria or other vesting provisions for such performance units or performance shares.

Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares or in some combination

Outside Directors. Our 2019 Plan will provide that all outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2019 Plan. In connection with our initial public offering, we implemented a formal policy pursuant to which our outside directors will be eligible to receive equity awards under our 2019 Plan. Our 2019 Plan includes a maximum annual limit of $500,000 of cash compensation and equity awards that may be paid, issued, or granted to an outside director in any fiscal year, increased to $1,000,000 for the fiscal year an individual initially becomes a member of our board of directors. For purposes of this limitation, the value of equity awards is based on the grant date fair value (determined in accordance with GAAP). Any cash compensation paid or equity awards granted to a person for his or her services as an employee, or for his or her services as a consultant (other than as an outside director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to our outside directors.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2019 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2019 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2019 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2019 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2019 Plan provides that in the event of a merger or change in control, as defined under our 2019 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant, or all awards of the same type, similarly.

In the event that a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse, all performance goals or other vesting criteria applicable to such award will be deemed achieved at 100% of target levels and such award will become fully exercisable, if applicable, for a specified period prior to the transaction, unless specifically provided for otherwise under the applicable award agreement or other written agreement with the participant. The award will then terminate upon the expiration of the specified period of time. If an option or stock appreciation right is not assumed or substituted, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

In addition, in the event of a change in control, each outside director's options and stock appreciation rights, if any, will vest fully and become immediately exercisable, all restrictions on his or her restricted stock and restricted stock units will lapse and all performance goals or other vesting requirements for his or her performance shares and units will be deemed achieved at 100% of target levels, and all other terms and conditions met.

Forfeiture and Clawback. All awards granted under our 2019 Plan will be subject to recoupment under any clawback policy that we are required to adopt under applicable law. In addition, the administrator will be able to provide in an award agreement that the recipient's rights, payments, and benefits with respect to such award will be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of specified events. In the event of any accounting restatement, the recipient of an award will be required to repay a portion of the proceeds received in connection with the settlement of an award earned or accrued under certain circumstances.

Amendment, Termination. The administrator will have the authority to amend, suspend or terminate the 2019 Plan provided such action will not impair the existing rights of any participant. Our 2019 Plan will automatically terminate in 2029, unless we terminate it sooner.

2019 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders have approved, our 2019 Employee Stock Purchase Plan, or ESPP. Our ESPP became effective in connection with our initial public offering in April 2019. We believe that allowing our employees to participate in our ESPP provides them with a further incentive towards ensuring our success and accomplishing our corporate goals.

The ESPP includes a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986, as amended, or the 423 Component, and a component that does not comply with Section 423, or the Non-423 Component. For purposes of this disclosure, a reference to the "ESPP" will mean the 423 Component. Unless determined otherwise by the administrator, each of our future non-U.S. subsidiaries, if any, will participate in a separate offering under the Non-423 Component.

Authorized shares. A total of 434,000 shares of our common stock are available for sale. In addition, our ESPP provides for annual increases in the number of shares available for issuance under the ESPP on the first day of each fiscal year beginning in fiscal year 2019, equal to the lesser of:

- 1% of the outstanding shares of our common stock on the last day of the previous fiscal year;
- 1,200,000 shares; or

- such other amount as may be determined by our board of directors.

Plan Administration. Our board of directors, or a committee appointed by our board of directors will administer our ESPP, and have full but non-exclusive authority to interpret the terms of our ESPP and determine eligibility to participate, subject to the conditions of our ESPP, as described below. Our compensation committee will administer our ESPP. The administrator will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, to delegate ministerial duties to any of our employees, to designate separate offerings under the ESPP, to designate our subsidiaries and affiliates as participating in the ESPP, to determine eligibility, to adjudicate all disputed claims filed under the ESPP and to establish procedures that it deems necessary or advisable for the administration of the ESPP, such as adopting such procedures, sub-plans, and appendices to the enrollment agreement as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the U.S. The administrator's findings, decisions, and determinations will be final and binding on all participants to the full extent permitted by law.

Eligibility. Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. The administrator will have the discretion prior to an enrollment date for all options granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date, (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (iv) is a highly compensated employee within the meaning of Section 414(v) of the Code or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- hold rights to purchase shares of our common stock under all of our employee stock purchase plans that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year.

Offering Periods. Our ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our ESPP. Our ESPP will provide for six-month offering periods. The offering periods will be scheduled to start on the first trading day on or after May 20th and November 20th of each year, except for the first offering period, which will commenced on the first trading day on or after completion of our initial public offering and will end on the first trading day on or after November 20, 2019. Each offering period will consist of one 6-month purchase period, which will commence with one exercise date and end with the next exercise date.

Contributions. Our ESPP will permit participants to purchase shares of our common stock through payroll deductions of up to 10% of their eligible compensation. A participant will be able to purchase a maximum of 2,000 shares of our common stock during a purchase period.

Exercise of Purchase Right. Amounts deducted and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. Participants will be able to end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to

purchase shares of our common stock. Participation will end automatically upon termination of employment with us.

Non-Transferability. A participant will not be able to transfer rights granted under our ESPP. If our compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution or as otherwise provided under our ESPP.

Merger or Change in Control. Our ESPP will provide that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator will have the authority to amend, suspend or terminate our ESPP, except that, subject to certain exceptions described in our ESPP, no such action may adversely affect any outstanding rights to purchase shares of our common stock under our ESPP. Our ESPP automatically will terminate in fiscal year 2039 unless we terminate it sooner.

2007 Stock Plan, as Amended

Our board of directors adopted, and our stockholders approved, our 2007 Stock Plan, or the 2007 Plan, in March 2007. Our 2007 Plan was most recently amended in June 2018. Our 2007 Plan allows for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options and shares of common stock to our employees, directors and consultants and our parent and subsidiary corporations' employees, directors and consultants.

Authorized Shares. Our 2007 Plan was terminated in connection with our initial public offering in April 2019, and accordingly, no shares are available for issuance under the 2007 Plan. Our 2007 Plan continues to govern outstanding awards granted thereunder. As of December 31, 2019, options to purchase 3,499,992 shares of our common stock remained outstanding under our 2007 Plan. In the event that an outstanding option or other right for any reason expires or is canceled, the shares allocable to the unexercised portion of such option or other right shall be added to the number of shares then available for issuance under the 2019 Plan once adopted by our board of directors and our stockholders.

Plan Administration. Our board of directors or a committee of our board (the administrator) administers our 2007 Plan. Subject to the provisions of the 2007 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2007 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2007 Plan.

Options. The 2007 Plan was terminated, and accordingly, no additional options may be granted under our 2007 Plan. Prior to the termination of the 2007 Plan the exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The term of a stock option may not exceed 10 years. With respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price per share of such incentive stock option must equal at least 110% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The 2007 Plan administrator determines the terms and conditions of options.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time as specified in the applicable option agreement. If termination is due to death or

disability, the option generally will remain exercisable for at least six months. In all other cases, the option will generally remain exercisable for at least 30 days. However, an option generally may not be exercised later than the expiration of its term.

Shares of Common Stock. Prior to the termination of the 2007 Plan shares of our common stock may be granted under our 2007 Plan as a purchasable award. The administrator will determine the purchase price and the number of shares granted to the award recipient. Stock purchase rights generally must be exercised within 90 days of grant.

Transferability of Awards. Unless our administrator provides otherwise, our 2007 Plan generally does not allow for the transfer or assignment of options or stock purchase rights, except by will or by the laws of descent and distribution. Shares issued upon exercise of an option will be subject to such terms and conditions as the administrator may determine, including rights of first refusal and other transfer restrictions.

Certain Adjustments. In the event of a subdivision of our outstanding stock, a declaration of a dividend payable in shares, a combination or consolidation of our outstanding stock into a lesser number of shares, a reclassification, or any other increase or decrease in the number of issued shares of stock effected without receipt of consideration by us, the 2007 Plan will be appropriately adjusted by the administrator as to the class and maximum number of securities subject to the 2007 Plan and the class, number of securities and price per share of common stock subject to outstanding awards under the 2007 Plan, provided that our administrator will make any adjustments as may be required by Section 25102(o) of the California Corporations Code.

Merger or Change in Control. Our 2007 Plan provides that, in the event that we are a party to a merger or change in control, outstanding options and stock purchase rights may be assumed or substituted by the successor corporation or a parent or subsidiary thereof. In the event the successor corporation refuses to assume or substitute for the option or stock purchase right, then the vesting of such awards will be fully accelerated and the administrator will notify the holder in writing or electronically that such awards will be fully exercisable and vested for a period as determined by the administrator, and such awards will terminate upon expiration of such period.

Amendment; Termination. Our board of directors terminated the 2007 Plan in April 2019 and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

NeuroCo, Inc. 2015 Equity Incentive Plan

In connection with our acquisition of NeuroCo, Inc. on December 17, 2018, our board of directors approved the assumption of the NeuroCo, Inc. 2015 Equity Incentive Plan, or the NeuroCo Plan.

Authorized Shares. The NeuroCo Plan was terminated on April 3, 2019, and, accordingly, no shares will be available for issuance under this plan. Our NeuroCo Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2019, options to purchase 857 shares of our common stock remained outstanding under the NeuroCo Plan.

Plan Administration. Our board of directors or a committee thereof appointed by our board of directors has the authority to administer the NeuroCo Plan. Subject to the provisions of the NeuroCo Plan, the administrator has the power to determine the terms of awards, including the recipients, the number of shares subject to each award, the exercise price, if any, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the terms of the award agreement for use under the NeuroCo Plan. The administrator also has the authority, subject to the terms of the NeuroCo Plan, to institute an exchange program under which (1) outstanding awards may be surrendered or cancelled in exchange for awards of the same type (which may have lower or higher exercise prices and different terms), awards of a different type and/or cash, (2) participants would have the opportunity to transfer any outstanding awards to a financial institution or

other person or entity selected by the administrator and/or (3) the exercise price of an outstanding award is increased or reduced, to prescribe rules and regulations pertaining to the NeuroCo Plan, including establishing sub-plans for the purposes of satisfying applicable foreign laws, and to construe and interpret the NeuroCo Plan and awards granted thereunder.

Stock Options. The NeuroCo Plan was terminated, and accordingly, no additional options may be granted under the NeuroCo Plan. Prior to the termination of the NeuroCo Plan the exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the date of grant. The term of an option may not exceed 10 years. An incentive stock option held by an employee who owns more than 10% of the total combined voting power of all classes of our stock, or any parent or subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our common stock on the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares, promissory notes or certain other property or other consideration acceptable to the administrator. After the termination of service of an employee, director or consultant, the participant may exercise his or her option, to the extent vested as of such date of termination, within 30 days of termination or such longer period of time as stated in his or her option agreement. If termination is due to death or disability, the option will remain exercisable, to the extent vested as of such date of termination, for six months or such longer period of time as stated in his or her option agreement. However, in no event may an option be exercised later than the expiration of its term.

Restricted Stock. The NeuroCo Plan was terminated, and accordingly, no restricted stock may be granted under the NeuroCo Plan. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeiture provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the administrator. Recipients of restricted stock awards will generally have rights equivalent to those of a stockholder with respect to such shares upon grant without regard to vesting.

Restricted Stock Units. The NeuroCo Plan was terminated, and accordingly, no restricted stock units may be granted under the NeuroCo Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units including the vesting criteria, which may include accomplishing specified performance criteria or continued service to us, and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion may accelerate the time at which any restrictions will lapse or be removed.

Stock Appreciation Rights. The NeuroCo Plan was terminated, and accordingly, no stock appreciation rights may be granted under the NeuroCo Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of shares of our common stock between the exercise date and the date of grant. Subject to the provisions of the NeuroCo Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Transferability of Awards. Unless the administrator provides otherwise, the NeuroCo Plan generally does not allow for the transfer of awards other than by will or the laws of descent and distribution and only the recipient of an option may exercise such an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the NeuroCo Plan, the administrator will adjust the number and class of shares that may be delivered under the NeuroCo Plan and/or the number, class and price of shares covered by each outstanding award. In the event of our proposed liquidation or

dissolution, the administrator will notify participants as soon as practicable, and all unexercised awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. The NeuroCo Plan provides that in the event of a merger or change in control, as defined under the NeuroCo Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that each award be assumed or substituted for an equivalent award. In the event that awards are not assumed or substituted for, then the administrator will notify holders that such awards will fully vest and such awards will become fully exercisable, if applicable, for a specified period prior to the transaction. The award will then terminate upon the expiration of the specified period of time for no consideration, unless otherwise determined by the administrator.

Amendment, Termination. As noted above, as of April 3, 2019, the NeuroCo Plan was terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

Executive Incentive Compensation Plan

Our board of directors has adopted an Executive Incentive Compensation Plan, or the Bonus Plan, which became effective upon the completion of our initial public offering in April 2019. The Bonus Plan is administered by our compensation committee. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation: (i) attainment of research and development milestones, (ii) bookings, (iii) business divestitures and acquisitions, (iv) cash flow, (v) cash position, (vi) contract awards or backlog, (vii) customer renewals, (viii) customer retention rates from an acquired company, subsidiary, business unit or division, (ix) earnings (which may include earnings before interest and taxes, earnings before taxes, and net taxes), (x) earnings per share, (xi) expenses, (xii) gross margin, (xiii) growth in stockholder value relative to the moving average of the S&P 500 Index or another index, (xiv) internal rate of return, (xv) market share, (xvi) net income, (xvii) net profit, (xviii) net sales, (xix) new product development, (xx) new product invention or innovation, (xxi) number of customers, (xxii) operating cash flow, (xxiii) operating expenses, (xxiv) operating income, (xxv) operating margin, (xxvi) overhead or other expense reduction, (xxvii) product defect measures, (xxviii) product release timelines, (xxix) productivity, (xxx) profit, (xxxi) retained earnings, (xxxii) return on assets, (xxxiii) return on capital, (xxxiv) return on equity, (xxxv) return on investment, (xxxvi) return on sales, (xxxvii) revenue, (xxxviii) revenue growth, (xxxix) sales results, (xl) sales growth, (xli) stock price, (xlii) time to market, (xliii) total stockholder return, (xliv) working capital, a (xlv) individual objectives such as peer reviews or other subjective or objective criteria, (xlvi) clinical quality metrics, (xlvii) regulatory milestones related to the U.S. Food and Drug Administration, Centers for Medicare and Medicaid Services, or other government agencies, (xlviii) intellectual property milestones, (xlix) physician training, and (l) any other goals or metrics related to the optimal management of a medical device company. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant’s actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant’s target

award, in the compensation committee's discretion. Our compensation committee may determine the amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid. Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. We 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, we have not made any matching or profits sharing contributions into the 401(k) plan. Beginning in January 2020, we started matching employees' contributions to the 401(k) plan at 50% of the first 5% of compensation deferred to the 401(k) plan. All participants' interests in their deferrals are 100% vested when contributed. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

Director Compensation

Prior to the completion of our initial public offering in April 2019, except for Donald Zurbay, non-employee members of our board of directors did not receive any cash compensation for service on our board of directors or committees, including attending board and committee meetings. However, we did reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in attending board, committee and other company related meetings. In addition, from time to time we have granted stock options to some of our directors.

Our Board of Directors approved our Outside Director Compensation Policy in April 2019 to compensate each non-employee director for his or her service. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or appropriate. Each non-employee director is eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards, as described below:

Cash Compensation. All non-employee directors are entitled to receive the following cash compensation for their services:

- $40,000 per year for services as a board member;
- $46,000 per year additionally for service as chairman of the board of directors;
- $20,000 per year additionally for service as chairman of the audit committee;
- $8,000 per year additionally for service as an audit committee member;
- $15,000 per year additionally for service as chairman of the compensation committee;
- $6,000 per year additionally for service as a compensation committee member;
- $5,000 per year additionally for service as a nominating and corporate governance committee member; and

- $9,000 per year additionally for service as chairman of the nominating and corporate governance committee.

Each annual cash retainer and additional annual fee is paid quarterly in arrears on a prorated basis.

Each non-employee director may also elect to receive all or part of his or her cash retainer and additional fee payments in the form of stock options under our 2019 Plan. Elections to receive cash retainer and additional fee payments in the form of options with respect to services to be performed during the period commencing on the date of an annual meeting of our stockholders, or an Annual Meeting, and ending on the following year's Annual Meeting must generally be made on or prior to December 31st of the year prior to the year in which such annual period commences, or such earlier deadline as established by our board of directors or compensation committee (an "annual election"). Each individual who first becomes a non-employee director is permitted to elect to convert cash retainer and additional fee payments payable in the same calendar year through the date of the following year's Annual Meeting into options, provided that the election is made prior to the date the individual becomes a non-employee director (an "initial election").

All options granted in lieu of cash retainer and additional fee payments will vest in quarterly installments that generally track when cash retainer or additional fee payments would have been paid, with the final vesting event occurring on the date of the next Annual Meeting following the date of grant. Options granted in connection with an annual election will generally be granted on the date of the next Annual Meeting following the calendar year in which the election is made. Options granted in connection with an initial election will generally be granted either on the fifth of the month following the month of the individual's election or appointment to our board of directors or on the date of the next Annual Meeting that occurs in the same calendar year as the individual's election or appointment to our board of directors.

Equity Compensation. Non-employee directors are entitled to receive all types of awards (except incentive stock options) under the 2019 Plan (or the applicable equity plan in place at the time of grant), including discretionary awards not covered under the Outside Director Compensation Policy. Nondiscretionary, automatic grants of stock options are made to our non-employee directors as follows:

- *Initial Option Grant*. Each person who first becomes a non-employee director will be granted an award of stock options with a value of $175,000.
- *Annual Option Grant*. Each non-employee director will be granted an award of stock options with a value of $100,000 on the date of each Annual Meeting, beginning with the 2020 Annual Meeting.

The "value" for the options described above means the grant date fair value calculated in accordance with the Black-Scholes option valuation methodology, or such other methodology our board of directors or compensation committee may determine. The term of each option described above will be ten years from the date of grant, subject to earlier termination as provided in the 2019 Plan. The exercise price per share of each option will equal the closing trading price of a share of our common stock on the date of grant.

Subject to the applicable provisions of the 2019 Plan as further described under the section titled "Employee Benefit and Stock Plans," (i) each Initial Option Grant will be scheduled to vest as to one-third of the shares subject to such Initial Option Grant on each annual anniversary of the date the applicable non-employee's service as a non-employee director commenced, subject to the non-employee director continuing to provide services to the Company through the applicable vesting date and (ii) each Annual Option Grant will be scheduled to vest on the earlier of (a) the annual anniversary of the date of grant of such Annual Option Grant, or (b) the day immediately prior to the Annual Meeting next following the date the Annual Option is granted, provided that for either (a) or (b), the non-employee director has remained in continuous service with the Company through the applicable vesting date. Additionally, pursuant to our Outside Director Compensation Policy, in the event of a change in control, each outstanding and

unvested equity award, including each Initial Option Grant and Annual Option Grant, held by a non-employee director who remains in continuous service through the date of such change in control will accelerate and fully vest.

Pursuant to our Outside Director Compensation Policy, no non-employee director may be issued, in any fiscal year, cash compensation and equity awards with an aggregate value greater than $500,000, increased to $1,000,000 for the fiscal year an individual initially becomes a member of our board of directors. Any cash compensation paid or equity awards granted to an individual for his or her services as an employee, for his or her services as a consultant (other than as a non-employee director), will not count for purposes of this limitation.

2019 Director Compensation Table

The following table sets forth a summary of the compensation received by our non-employee directors during our fiscal year ended December 31, 2019:

Name	Fees Earned or Paid in Cash ($) [1]	Option Awards ($) [2][3]	Total ($)
Ruoxi Chen	$ 31,500	$ 102,903	$ 134,403
Tony M. Chou, M.D.	23,333	97,071	120,404
Amr Kronfol	23,333	97,071	120,404
Jack W. Lasersohn	32,756	103,312	136,068
Robert E. Mittendorf, M.D.	26,833	99,560	126,393
Elizabeth H. Weatherman	29,212	100,395	129,607
Donald J. Zurbay	51,168	80,411	131,579

(1) The amounts reported represent the aggregate dollar amount of all fees earned or paid in cash to each non-employee director for their service as a director during fiscal year 2019, including any annual retainer fees, committee and/or chairmanship fees. Certain non-employee directors elected to receive their cash retainer and additional fee payments in the form of stock options. The fair value of stock option awards received in lieu of cash was $53,992 for Mr. Chen, $39,994 for Dr. Chou, $39,994 for Mr. Kronfol, $54,984 for Mr. Lasersohn, $45,983 for Dr. Mittendorf, and $47,985 for Ms. Weatherman.

(2) The amount reported represents the aggregate grant-date fair value of the stock options awarded, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Common Stock Valuation and Stock-Based Compensation."

(3) These amounts include the additional value of the option awards received by Mr. Chen ($22,492), Dr. Chou ($16,660), Mr. Kronfol ($16,660), Mr. Lasersohn ($22,900), Dr. Mittendorf ($19,149), and Ms. Weatherman ($19,985) in connection with their respective elections to receive their cash retainers and additional fees in the form of stock options.

Options outstanding as of December 31, 2019, held by our non-employee directors were as follows:

Name	Shares Subject to Outstanding Options
Ruoxi Chen	11,849
Tony M. Chou, M.D.	11,087
Amr Kronfol	11,087
Jack W. Lasersohn	11,903
Robert E. Mittendorf, M.D.	11,413
Elizabeth H. Weatherman	46,707
Donald J. Zurbay	184,147

Directors who are also our employees receive no additional compensation for their service as directors. During 2019, Erica J. Rogers, who is one of our directors, was also an employee of our

company. See “Executive Compensation—Summary Compensation Table” for additional information about the compensation for Ms. Rogers.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board of directors has been one of our employees within the past five years.

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

The following table provides information concerning beneficial ownership of our common stock as of February 28, 2020, by:

- Each stockholder, or group of affiliated stockholders, that we know owns more than 5% of our outstanding common stock;
- Each of our executive officers;
- Each of our directors; and
- All of our executive officers and directors as a group.

The percentage of shares beneficially owned is computed on the basis of 31,353,906 shares of our common stock outstanding as of February 28, 2020. Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power or investment power with respect to the securities held. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of February 28, 2020, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Except as indicated in the footnotes to this table, (i) the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them, and (ii) the address for each beneficial owner is c/o Silk Road Medical, Inc., 1213 Innsbruck Dr, Sunnyvale, CA 94089.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares**	**Percentage**
5% and Greater Stockholders:		
Entities affiliated with Warburg Pincus & Co[1]	5,906,301	18.8%
Entities affiliated with Wells Fargo & Company[2]	2,309,767	7.4%
Entities affiliated with Janus[3]	1,928,928	6.2%
Executive Officers and Directors:		
Erica J. Rogers[4]	1,117,890	3.5%
Lucas W. Buchanan[5]	435,024	1.4%
Andrew S. Davis[6]	238,338	*
Richard M. Ruedy[7]	198,994	*
Elizabeth H. Weatherman[8]	303,742	1.0%
Tony M. Chou, M.D.[9]	97,799	*
Ruoxi Chen[10]	2,204	*
Amr Kronfol[11]	1,632	*
Jack W. Lasersohn[12]	7,304	*
Robert E. Mittendorff, M.D.[13]	1,877	*
Donald J. Zurbay[14]	91,268	*
All executive officers and directors as a group (11 persons)[15]	2,496,072	7.8%

* Represents ownership of less than 1%.

(1) Consists of (i) 183,090 shares of common stock beneficially owned by Warburg Pincus X Partners, L.P. (“WPXP”), and (ii) 5,723,211 shares of common stock beneficially owned by WP X Finance, L.P. (“WP X Finance”). WPX GP, L.P., a Delaware limited partnership (“WPX GP”), is the managing general partner of WP X Finance. Warburg Pincus Private Equity X, L.P., a Delaware limited partnership (“WP X”), is the general

partner of WPX GP. Warburg Pincus X, L.P., a Delaware limited partnership ("WPX LP"), is the general partner of WPX and WPXP. Warburg Pincus X GP L.P., a Delaware limited partnership ("WP X GP LP"), is the general partner of WPX LP. WPP GP LLC, a Delaware limited liability company ("WPP GP"), is the general partner of WP X GP LP. Warburg Pincus Partners, L.P., a Delaware limited partnership ("WP Partners"), is the managing member of WPP GP. Warburg Pincus Partners GP LLC, a Delaware limited liability company ("WP Partners GP"), is the general partner of WP Partners. Warburg Pincus & Co., a New York general partnership ("WP"), is the managing member of WP Partners GP. The business address for each of these entities and individuals is c/o Warburg Pincus & Co., 450 Lexington Avenue, New York, New York 10017.

Ruoxi Chen, a Principal at Warburg Pincus & Co., and Amr Kronfol, a Managing Director at Warburg Pincus & Co., are members of our board of directors, and both have no voting or dispositive power with respect to any of the above referenced shares and each disclaims beneficial ownership of such shares except to the extent of his or her respective pecuniary interest therein. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein.

(2) Consists of 2,309,767 shares of common stock held by entities affiliated with Wells Fargo and Company, based on information provided by Wells Fargo and Company in Schedule 13G filed with the SEC on February 4, 2020.

(3) Consists of 1,928,928 shares of common stock held by entities affiliated with Janus Henderson Group PLC, based on information provided by Janus Henderson Group PLC in Schedule 13G filed with the SEC on February 14, 2020. The shares owned by Janus Henderson Capital Fund, Janus Henderson Global Life Sciences Fund and Buoybreeze (collectively, the "Funds") may be deemed to be beneficially owned by Janus Capital Management LLC ("Janus"), an investment advisor registered under the Investment Advisers Act of 1940, who acts as investment adviser for the Funds set forth above and has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of trustees (or similar entity) of each Fund. Under the terms of its management contract with each Fund, Janus has overall responsibility for directing the investments of the Fund in accordance with the Fund's investment objective, policies and limitation. Each Fund has one or more portfolio managers appointed by and serving at the pleasure of Janus who makes decisions with respect to the disposition of the Shares. The address for Janus is 151 Detroit Street, Denver, CO 80206.

(4) Consists of (i) 97,546 shares of common stock held directly by Ms. Rogers, (ii) 83,843 shares of common stock held by Kevin J. Surace and Erica J. Rogers, as Trustees of The Surace/Rogers Family Trust, and (iii) 936,501 shares of common stock issuable pursuant to options held directly by Ms. Rogers exercisable within 60 days of February 28, 2020.

(5) Consists of (i) 89,410 shares of common stock held directly by Mr. Buchanan, (ii) 13,518 shares of common stock held by the Buchanan Grandchildren's Irrevocable Trust, and (iii) 332,096 shares of common stock issuable pursuant to options held directly by Mr. Buchanan exercisable within 60 days of February 28, 2020.

(6) Consists of (i) 13,540 shares of common stock held directly by Mr. Davis, and (ii) 224,798 shares of common stock issuable pursuant to options held directly by Mr. Davis exercisable within 60 days of February 28, 2020.

(7) Consists of (i) 7,794 shares of common stock held directly by Mr. Ruedy, (ii) 70 shares of common stock held by Linda Ruedy, and (iii) 191,130 shares of common stock issuable pursuant to options held directly by Mr. Ruedy exercisable within 60 days of February 28, 2020.

(8) Consists of (i) 275,394 shares of common stock held directly by Ms. Weatherman, and (ii) 28,348 shares of common stock issuable pursuant to options held directly by Ms. Weatherman and exercisable within 60 days of February 28, 2020.

(9) Consists of (i) 96,197 shares of common stock held directly by Dr. Chou, and (ii) 1,632 shares of common stock issuable pursuant to options held directly by Dr. Chou exercisable within 60 days of February 28, 2020.

(10) Consists of 2,204 shares of common stock issuable pursuant to options held directly by Mr. Chen exercisable within 60 days of February 28, 2020.

(11) Consists of 1,632 shares of common stock issuable pursuant to options held directly by Mr. Kronfol exercisable within 60 days of February 28, 2020.

(12) Consists of (i) 5,060 shares of common stock held directly by Mr. Lasersohn, and (ii) 2,244 shares of common stock issuable pursuant to options held directly by Mr. Lasersohn exercisable within 60 days of February 28, 2020.

(13) Consists of 1,877 shares of common stock issuable pursuant to options held directly by Dr. Mittendorf exercisable within 60 days of February 28, 2020.

(14) Consists of 91,268 shares of common stock issuable pursuant to options held directly by Mr. Zurbay exercisable within 60 days of February 28, 2020.

(15) Consists of (i) 682,342 shares of common stock and common stock purchase warrants held by our current directors and officers and entities affiliated with certain of our current directors and officers, and (ii) 1,813,730 shares of common stock issuable pursuant to stock options held by such directors and officers and exercisable within 60 days of February 28, 2020.

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2019. Information is included for equity compensation plans approved by our stockholders. We do not have any equity compensation plans not approved by our stockholders.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights[2]	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plan Approved by Stockholders [1]	4,310,790	$ 7.91	1,927,042
Equity Compensation Plan Not Approved by Stockholders	—	$ —	—
Total	4,310,790		1,927,042

(1) Includes the following plans: 2007 Stock Option Plan, NeuroCo 2015 Equity Incentive Plan, 2019 Equity Incentive Plan ("2019 Plan"), and 2019 Employee Stock Purchase Plan ("2019 ESPP"). Our 2019 Plan provides that on January 1st of each fiscal year commencing in 2020 and ending on (and including) January 1, 2029, the number of shares authorized for issuance under the 2019 Plan is automatically increased by a number

equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year or; (iii) such other amount as our board of directors may determine. Our 2019 ESPP provides that on January 1st of each fiscal year commencing in 2020 and ending on (and including) January 1, 2039, the number of shares authorized for issuance under the 2019 ESPP is automatically increased by a number equal to the lesser of (i) 434,000 shares; (ii) 1.0% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as our board of directors may determine.

(2) The weighted average exercise price relates solely to outstanding stock option shares.

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

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2017, to which we were a party or will be a party, in which:

- The amounts involved exceeded or will exceed $120,000; and
- Any of our directors, executive officers, or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and named executive officers are described elsewhere in this Annual Report on Form 10-K.

Certain Transactions with Related Persons

During 2017 and 2018, the wife of Richard Ruedy, Executive Vice President of Clinical and Regulatory Affairs and Quality Assurance, was employed by the Company as Senior Director of Clinical and Regulatory Affairs. In 2017, Mr. Ruedy's wife earned total compensation of $204,883. In 2018, Mr. Ruedy's wife earned total compensation and severance of $315,900. Total compensation includes salary and bonus. In 2019, Mr. Ruedy's wife transitioned to a regulatory consultant at a rate of $30,000 per month through March 31, 2019. The compensation of Mr. Ruedy's wife was consistent with that of other employees with equivalent qualifications and responsibilities and holding similar positions, and Mr. Ruedy recused himself from any decision regarding the hiring of, or compensation related to his wife.

Series C Preferred Stock Financing

Between August 2014 and July 2017, we issued an aggregate 12,227,992 shares of our Series C preferred stock at a purchase price of $6.11 per share. The aggregate purchase price in the table below reflects the price paid for the Series C preferred stock only and not for the warrants. The shares of Series C preferred stock converted into an aggregate of 12,227,992 shares of common stock upon the completion of our initial public offering. The table below sets forth the number of shares of Series C preferred stock and the number of warrant shares issued in connection with our Series C preferred stock financing to our directors, executive officers and holders of more than 5% of our capital stock:

Name	Number of Shares	Number of Warrant Shares	Aggregate Purchase Price
Entities affiliated with Warburg Pincus & Co.(1)	5,904,180	2,214,626	$ 36,027,324.24
Entities affiliated with Janus(2)	2,458,210	—	14,999,999.68
Entities affiliated Norwest Venture Partners(3)	2,458,210	—	14,999,999.68
Entities affiliated with The Vertical Group, Inc.(4)	656,015	246,067	4,003,022.74
Elizabeth H. Weatherman	163,880	40,970	999,995.76
Erica J. Rogers(5)	9,012	1,638	54,997.10
Lucas W. Buchanan(6)	18,843	4,915	114,993.32
Andrew S. Davis	12,290	—	74,998.10

(1) Affiliates of Warburg Pincus holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are WP X Finance, L.P., which purchased 5,721,152 shares, and Warburg Pincus X Partners, L.P., which purchased 183,028 shares.
(2) Affiliates of Janus holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are Buoybreeze + Co (a State Street Nominee), which purchased 1,610,446 shares, and Janus Capital Funds PLC on behalf of its Series Janus Global Life Sciences Fund, which purchased 847,764 shares.
(3) The affiliate of Norwest Venture Partners holding our securities is Norwest Venture Partners XIII, LP, which purchased 2,458,210 shares.
(4) Affiliates of the Vertical Group holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are Vertical Fund I, L.P., which purchased 524,814 shares, and Vertical Fund II, L.P., which purchased 131,201 shares.
(5) Includes 9,012 shares held of record by The Surace/Rogers Family Trust, of which Erica J. Rogers, one of our executive officers, serves as trustee.
(6) Includes 10,651 shares held of record by the Buchanan Grandchildren's Irrevocable Trust, of which Mr. Buchanan, one of our executive officers, serves as trustee.

Stockholders Agreement

In July 2017, in connection with the final closing of our Series C preferred stock financing, we entered into an amended and restated stockholders agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated.

Registration Rights Agreement

In July 2017, in connection with the final closing of our Series C preferred stock financing, we entered into an amended and restated registration rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. The amended and restated registration rights agreement was amended on March 21, 2019. For a detailed description of registration rights under this agreement (as amended), see "Description of Capital Stock—Registration Rights." Upon the completion of our initial public offering in April 2019, the information rights and right of first refusal under the stockholders agreement terminated.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties, fines and settlement amounts incurred by the director or officer in any action or proceedings, including any action or proceeding by or in right of us, arising out of the person's service as a director or officer. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

NeuroCo Merger

We established a holding company, NeuroCo, Inc., to hold certain intellectual property and to undertake certain research and development activities. On December 17, 2018, we and NeuroCo entered into an Agreement and Plan of Merger pursuant to which we acquired all assets, including the assignment of all patents, and assumed all liabilities of NeuroCo. The merger closed on the same day and was consummated through a stock-for-stock transaction based on the relative values of our equity and NeuroCo's equity. In consideration for 100% equity interest of NeuroCo, we issued 33,462 shares of our common stock, and a promissory note in the principal amount of approximately $1.6 million was settled and canceled. We assumed NeuroCo's 2015 Equity Incentive Plan, or the NeuroCo Plan. As of the merger closing, the outstanding options to purchase common stock of NeuroCo under the NeuroCo Plan converted to options to purchase 1,442 shares of our common stock, and all outstanding warrants to purchase common stock of NeuroCo converted to warrants to purchase 7,527 shares of our common stock. As a result of the merger, NeuroCo merged into our company, with our company being the surviving corporation.

Policies and Procedures for Related Party Transactions

Our board of directors has approved a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. We did not have a formal review and approval policy for related party transactions at the time of any of the transactions described above. However, all of the transactions described above were entered into after presentation, consideration and approval by our board of directors.

Item 14. Principal Accounting Fees and Services

The following table presents fees for professional audit services and other services billed to us by PricewaterhouseCoopers LLP, or PwC, for our fiscal years ended December 31, 2019 and 2018:

Year Ending December 31,	2019	2018
Audit fees[1]	$ 1,774,000	$ 641,000
Audit related fees	—	—
Tax fees	—	—
All other fees	1,000	22,000
Total	$ 1,775,000	$ 663,000

(1) Audit fees consist of professional services rendered for the audits of our financial statements and reviews of quarterly financial statements. The audit fees incurred in 2019 also include fees of $857,000 related to services performed in connection with our initial public offering, which was completed in April 2019 and our follow-on offering, which was completed in August 2019, and review of documents filed with the SEC.

Auditor Independence

In our fiscal year ended December 31, 2019, there were no other professional services provided by PwC that would have required our audit committee to consider their compatibility with maintaining the independence of PwC.

Audit Committee Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee expects to establish a policy governing our use of the services of our independent registered public accounting firm. Under this policy, our audit committee will be required to pre-approve all audit and non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair the public accountants' independence. All fees paid to PwC for our fiscal years ended December 31, 2019 and 2018 were pre-approved by our audit committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 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.

(b) Financial Statement Schedules.

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 and the provision for sales returns for the years ended December 31, 2019 and 2018 (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, 2019	$ 22	$ 23	$ —	$ 45
Year ended December 31, 2018	$ 149	$ (123)	$ 4	$ 22

Description	Balance at Beginning of Year	Charged to expenses	Write offs	Balance at End of Year
Provision for sales returns:				
Year ended December 31, 2019	$ 1,862	$ 1,765	$ 1,208	$ 2,419
Year ended December 31, 2018	$ 462	$ 1,958	$ 558	$ 1,862

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	
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 (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 2, 2020	By:	/s/ Erica J. Rogers
		Erica J. Rogers *President, Chief Executive Officer and Director* *(Principal Executive Officer)*
March 2, 2020	By:	/s/ Lucas W. Buchanan
		Lucas W. Buchanan *Chief Financial Officer* *(Principal Financial Officer and Principal Accounting Officer)*

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 2, 2020
/s/ Lucas W. Buchanan Lucas W. Buchanan	Chief Financial Officer (Principal Financial Officer)	March 2, 2020
/s/ Ruoxi Chen Ruoxi Chen	Director	March 2, 2020
/s/ Tony M. Chou Tony M. Chou, M.D.	Director	March 2, 2020
/s/ Amr Kronfol Amr Kronfol	Director	March 2, 2020
/s/ Jack W. Lasersohn Jack W. Lasersohn	Director	March 2, 2020
/s/ Robert E. Mittendorff Robert E. Mittendorff, M.D.	Director	March 2, 2020
/s/ Elizabeth H. Weatherman Elizabeth H. Weatherman	Director	March 2, 2020
/s/ Donald J. Zurbay Donald J. Zurbay	Director	March 2, 2020

Exhibit 4.5

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Silk Road Medical, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.001 per share.

As used in this summary, the terms "Silk Road Medical," "the Company," "we," "our" and "us" refer to Silk Road Medical, Inc.

Description of Common Stock

The following is a description of the material terms and provisions relating to our common stock. The following description is a summary that is not complete and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and our amended and restated bylaws, and to provisions of the Delaware General Corporation Law. Copies of our amended and restated certificate of incorporation and our amended and restated bylaws, each of which may be amended from time to time, are included as exhibits to the Annual Report on Form 10-K to which this description is an Exhibit.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

Dividends

Subject to preferences that may be applicable to any then outstanding convertible preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of convertible preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Anti-Takeover Effects or Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that are in effect contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stock holders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of a non-friendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- Before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

- Upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- On or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- Any merger or consolidation involving the corporation and the interested stockholder;

- Any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- Subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- Any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- The receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our board of directors, the chairperson of our board of directors, or our Chief Executive Officer or President. This provision might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our common stock to take any action, including the removal of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice.

Advance Notice of Stockholder Business

If a stockholder is submitting a stockholder proposal related to the business of the company, such stockholder must: (i) be a stockholder of record at the time notice is given, (ii) submit the notice in a timely manner, and (iii) such business must be of a proper matter for stockholder action in accordance with our bylaws and applicable law. To be in proper written form, a stockholder's notice related to the business of the company must contain the following items: (i) a brief description of the business intended to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (ii) the name and address of the stockholder proposing such business, (iii) the class and number of shares that are held of record or are beneficially held by the stockholder, (iv) whether and the extent to which any hedging activities have been entered into by or on behalf of such stockholder with respect to our securities, (v) any material interest of the stockholder in such business, (vi) a statement whether such stockholder will deliver a proxy statement or form of proxy to holders required under applicable law to carry the proposal.

Advance Notice of Director Nominations

If a stockholder is submitting a nomination in connection with an annual meeting, such stockholder must: (i) be a stockholder of record at the time notice if given, and (ii) submit the notice in a timely manner. To be in proper written form, a stockholder's notice related to director nominations must contain the following items with respect to each nominee: (i) the name, age, business address and residence address of the nominee, (ii) the principal occupation or employment of the nominee, (iii) the class and number of shares of the company that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (iv) whether and the extent to which any hedging activities have been entered into by or on behalf of the nominee with respect to our securities, (v) a description of all arrangements or understandings between or among the stockholder, any nominee or any other person or persons pursuant to which the nominations are to be made by the stockholder and (vi) a written statement executed by the nominee acknowledging and representing that the nominee intends to serve a full term on our board of directors if elected. With respect to the stockholder, the notice must contain the following items: (i) the name and address of the stockholder proposing such business, (ii) the class and number of shares that are held of

record or are beneficially held by the stockholder, (iii) whether and the extent to which any hedging activities have been entered into by or on behalf of such stockholder with respect to our securities, (iv) any material interest of the stockholder in such business, and (v) a statement whether such stockholder will deliver a proxy statement or form of proxy reasonably believed by such stockholder to be necessary to elect such nominee.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting. As a result, a holder controlling a majority of our common stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws.

Classified Board; Election and Removal of Directors

Our amended and restated certificate of incorporation and amended and restated bylaws authorizes only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors are permitted to be set only by a resolution adopted by our board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors up for election. In addition, our amended and restated certificate of incorporation provides that directors may only be removed for cause. For more information on the classified board, see the section entitled “Management—Board of Directors” in our Annual Report on Form 10-K to which this description is an Exhibit. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Exclusive Forum

Our amended and restated certificate of incorporation and bylaws provides 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, our amended and restated certificate of incorporation or bylaws, or (4) 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. Any person or entity purchasing or otherwise acquiring any interest in our shares of common 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.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the voting power of our then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exchange Listing

Our common stock is quoted on The Nasdaq Global Market under the symbol “SILK.”

Transfer Agent

The transfer agent for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, NY 11219.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-230778) of Silk Road Medical, Inc. of our report dated March 2, 2020 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 2, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

I, Erica J. Rogers, certify that:

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

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

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

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

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

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

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

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

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

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

/s/ Erica J. Rogers

Erica J. Rogers
Chief Executive Officer

(Principal Executive Officer)

Date: March 2, 2020

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Lucas W. Buchanan, certify that:

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

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

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

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

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

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

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

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

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

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

/s/ Lucas W. Buchanan

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

Date: March 2, 2020

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Silk Road Medical, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

/s/ Erica J. Rogers

Erica J. Rogers
Chief Executive Officer
(Principal Executive Officer)

Date: March 2, 2020

/s/ Lucas W. Buchanan

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

Date: March 2, 2020