

Risk Factors Comparison 2024-02-28 to 2023-02-28 Form: 10-K

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We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes. Please also see “Cautionary Note Regarding Forward-Looking Statements.” Summary of Principal Risk Factors The following risks and uncertainties are among the most significant we face. However, the risks and uncertainties identified in this subsection are not the only ones we face and are qualified in their entirety by reference to all of the risk factors as further described in this Item 1A. Risks Related to Our Business • We have a history of net losses, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. • We rely on, and currently sell products to enable, TCAR, which is our only product offering. • Our business is dependent upon the **total market opportunity for TCAR and our ability to penetrate it through** continued adoption of TCAR by hospitals and physicians. • Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business. • Global supply chain constraints and constrained labor markets **have resulted and**, ~~including those caused by COVID-19,~~ could **continue to** result in the inability of our suppliers to deliver finished goods, components, sub-assemblies or materials to us on a timely basis or at all. • **We rely on Cordis to supply the ENROUTE stent, and if Cordis fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.** • General macroeconomic factors, including inflation, price pressures and ~~the risk of a recession~~ **recessionary pressures**, could increase our manufacturing costs and operating expenses or lower demand for our TCAR products and have a material adverse impact on our financial condition and results of operations. • If we are not able to obtain or maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or if patients are left with significant out-of-pocket costs, it would have a material adverse effect on our business, financial condition and results of operations. • If we fail to comply with our obligations in our intellectual property license from Cordis, we could lose license rights that are important to our business. • ~~We rely on Cordis to supply the ENROUTE stent, and if Cordis fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.~~ • TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption. • We face manufacturing risks that could adversely affect our ability to manufacture products, reduce our gross margins and negatively affect our business and operating results. • We depend on a limited number of single-source suppliers to manufacture our components, sub-assemblies, materials and products, including Cordis, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations. • We face risks related to health epidemics and other outbreaks, such as ~~the~~ **possible resurgences of** COVID-19 pandemic and the spread of new variants, which may negatively impact our business and operations. • The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business. • Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. • **The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments that are safer, more effective or gain greater acceptance in the marketplace than any products we develop, our commercial opportunities will be reduced or eliminated.** • **We are highly dependent upon our sales personnel. In addition, during 2023, we expanded our sales and marketing infrastructure, including the number of sales personnel and sales territories, to help us drive and support revenue growth. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023 and may continue to adversely affect our revenue through the first half of 2024.** • **Our actual operating results have differed in the past, and in the future may differ, significantly from our guidance, which has caused, and could continue to cause, the market price of our common stock to decline.** • **Our failure to manage the transition associated with our Chief Executive Officer, retain our existing senior management team, or continue to attract qualified new personnel could have a material adverse effect on our business.** Risks Related to Our Intellectual Property • We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products. • Our success depends on our ability to obtain, maintain and protect our intellectual property rights. Risks Related to Government Regulation • Healthcare policy changes, including ~~recently enacted~~ legislation reforming the U. S. healthcare system, could harm our business, financial condition and results of operations. • Our products have in the past and could in the future be subject to product recalls that could harm our reputation or increase the probability of inspection by, or additional scrutiny from, the FDA or other relevant regulatory bodies. • Changes in the CMS fee schedules **and other reimbursement requirements, such as those in revised NCD 20.7,** may affect our hospital customers and thereby harm our revenue and operating results. Risks Related to Our Business We have a history of net losses, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have incurred net losses since our inception in March 2007. For the year ended December 31, ~~2022~~ **2023**, we had a net loss of \$ 55. ~~0~~ **7**

million and we expect to continue to incur additional losses in the future. As of December 31, 2022-2023, we had an accumulated deficit of \$ 343-399.7-5 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts, investments in manufacturing and distribution capacity, and other infrastructure improvements. Over the next several years, we expect to continue to devote a substantial amount of our resources to increase adoption of TCAR using our products, expand commercialization efforts in the United States and select international markets, improve and expand reimbursement for TCAR, conduct clinical studies, and develop additional products. **No assurance can be provided that our strategic initiatives will be successful or lead us to profitability.** In addition, as a public company, we incur significant legal, accounting, director and officer liability insurance and other expenses, all of which continue to increase. **Our ability to generate sufficient revenue from our existing products or from any of our products in development, to transition to profitability and generate consistent positive cash flows, is uncertain.** Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future **or within a timeline expected by investors** will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. **While we believe we will continue to grow our revenues, we may be unable to sustain our historical revenue growth. Our revenue from sales of our TCAR products has grown in each of the fiscal years since we began commercialization in 2015 and we believe it will continue to grow. Historically, we have experienced significant revenue growth but we may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior quarterly or annual period as an indication of our future operating performance. Our ability to increase our revenue in future periods at our historical growth rates, or at all, will depend primarily on our ability to increase sales of our TCAR products, which, in turn, will depend in part on our success in growing our customer base and reorders from those customers. We may not be able to generate, sustain or increase revenue from our TCAR products on a quarterly or annual basis. If we cannot achieve or sustain revenue growth for an extended period, our operating results may be adversely affected and our stock price may decline. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a shortfall relative to our anticipated revenue could magnify the adverse impact of such shortfalls on our results of operations.** We rely on, and currently sell products to enable, TCAR, which is our only product offering. To date, all of our revenue has been derived, and we expect it to continue to be derived in the near term, from sales of our products that enable TCAR. TCAR is a relatively new treatment option for certain patients diagnosed with carotid artery disease and, as a result, physician awareness of TCAR and our products, and experience with TCAR and our products, is limited. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including: • Physician experience and hospital demand for our products and the extent of adoption of TCAR, including the rate at which physicians recommend our products and TCAR to their patients; • Failure of our products that enable TCAR to significantly penetrate the target markets; • Delays in, or failure to supply product, component and material deliveries by our third- party suppliers; • Positive or negative media coverage, or public, patient and / or physician perception, of our products and TCAR or competing products and procedures; • Any **product quality, recall,** safety or effectiveness concerns that arise regarding our products or TCAR; • Unanticipated delays in product development or product launches; • Our ability to maintain our current or obtain further regulatory clearances or approvals; • **Adequate levels of third- party coverage and reimbursement for the procedures using our products;** and • Introduction of new products ~~or,~~ **procedures or drugs** for treating carotid artery disease that compete with our products and the TCAR procedure, **including without limitation, the approval or substitution of other stents that could be used in TCAR procedures and the effect of competing products on the average selling prices of our products, and changes in reimbursement for our products and competing products.** It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding **the market opportunity for TCAR or** the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer. In addition, because we devote substantially all of our resources to our products that enable TCAR and rely on our products and the adoption of TCAR as our sole source of revenue, any factors that negatively impact our products or TCAR, or result in a decrease in sales of products, could have a material adverse effect on our business, financial condition and results of operations. Our business is dependent upon the **total market opportunity for TCAR and our ability to penetrate it through** continued adoption of TCAR by hospitals and physicians. Our future growth and profitability largely depend on **the total market opportunity for TCAR, the determination of which is inherently imprecise, and our ability to penetrate it, which is largely dependent upon** our ability to increase physician awareness and adoption of TCAR and on the willingness of physicians to recommend the procedure to more of their patients. **While we are confident in our estimate of the annual total addressable market for our TCAR products, especially since it is based on a number of internal and third- party estimates, it may prove to be incorrect. If the actual number of patients who would benefit from our products and the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. With respect to our ability to penetrate this market opportunity, Physicians** **physicians** may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery

disease. Even if we are able to raise awareness and increase adoption of TCAR among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products or TCAR for recommendation to patients for a variety of reasons, including:

- Long- standing relationships with competing companies and distributors that sell other products, such as stents and embolic protection devices for CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long- term data **or a randomized controlled trial**, supporting clinical benefits;
- **Familiarity and Lack of** experience with Carotid Endarterectomy, or **TCAR as a treatment alternative to CEA;**
- **Familiarity and experience with** CEA, and reluctance to change to or use new products and procedures; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with TCAR and our products.

While we believe the revised NCD 20. 7 for Percutaneous Transluminal Angioplasty will lead to benefit carotid artery disease awareness in general and help grow the overall carotid intervention market, which would be a potential positive for all carotid interventions, including TCAR, no assurance can be provided that this will prove true. In addition, while we believe the higher associated procedural stroke risk for transfemoral carotid artery stenting and steep learning curve will continue to limit the pool of eligible patients and skilled interventionalists, thereby limiting the growth potential for transfemoral CAS in the near term, no assurance can be provided that this will prove true either. During CMS review of the clinical literature and as suggested by the Multispecialty Carotid Alliance, or MSCA, CMS considered evidence published from the ACT I, CREST (long- term results), SPACE- 2 and ACST- 2 randomized controlled trials of CAS versus CEA, amongst other datasets. As well, in November 2023, preliminary results of newer CAS technologies in the PERFORMANCE II and C- Guardians IDE studies were presented at the late- breaking trials session Vascular InterVentional Advances, or VIVA, conference. Physicians may find these data compelling and may be more willing to try the newer transfemoral CAS products at the expense of our TCAR procedure, especially in the near term and as a result of revised NCD 20. 7. Accordingly, it is possible that we may experience increased future competition from stents and embolic protection devices for CAS based on the revised NCD 20. 7, which could adversely affect our revenue, other financial results and business.

Physicians play a significant role in determining the course of a patient's treatment for carotid artery disease and, as a result, the type of treatment that will be recommended or provided to a patient. **This is particularly true in light of the new requirement in revised NCD 20. 7 which requires a practitioner to engage in a shared decision- making interaction with the beneficiary prior to furnishing CAS.** We focus our sales, marketing and education efforts primarily on vascular surgeons, and aim to educate referring physicians such as **internal medicine specialties**, cardiologists, radiologists, neurologists, and general practitioners regarding the patient population that would benefit from TCAR. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if diagnosing physicians who serve as the primary point of contact for patients are not made aware of TCAR, they may not refer patients to physicians for treatment using our products, and those patients may instead not seek treatment at all or may be treated with alternative procedures. In addition, some physicians may choose to utilize TCAR on only a subset of their total patient population or may not adopt TCAR at all. If a physician experiences an adverse event in one or more of their TCAR patients or elects to convert TCAR to CEA mid- procedure, they may not continue offering and performing TCAR at the same rate or at all. Further, TCAR may not fit into the workstreams of certain physicians. If we are not able to effectively demonstrate that TCAR is beneficial in a broad range of patients, adoption of TCAR will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that TCAR or our products will achieve broad market acceptance among hospitals and physicians. Any failure of TCAR or our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations. In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of the Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business. In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, if patient receptivity toward TCAR becomes less favorable in the future, this shift could negatively impact market acceptance of TCAR. Any negative change due to patient receptivity could also be compounded by patients reporting to physicians or other patients through word- of- mouth or social media. Finally, the total market opportunity for TCAR could decrease if glucagon- like peptide (GLP- 1) agonists are prescribed more broadly and result in less cardiovascular disease including carotid artery disease and overall fewer strokes over the long term.

Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business. The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's, or the SVS's Vascular Quality Initiative contains real world data retrospectively comparing carotid revascularization procedures including TCAR, we have not conducted **a randomized clinical trial of TCAR or** head- to- head clinical trials to prospectively compare TCAR to the procedures historically available to patients, such as CEA or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis 2, or CREST- 2, clinical trial currently

funded by the National Institutes of Health, is ongoing and is designed to compare the effectiveness of each of CEA and CAS, in parallel randomized trials, with best medical therapy alone in standard surgical risk asymptomatic patients with carotid artery disease. **The CEA trial completed enrollment in the fourth quarter of 2023.** We estimate that **project the CAS trial to complete** enrollment **later in** will not be completed until sometime between 2023-2024 -2025, followed by a mean follow-up period of four years. **The national principal investigators have stated that results will not be published until 2026.** After the follow-up period post final enrollment, the trial could conclude that medical management alone achieves the same **or better** therapeutic results as CEA and / or CAS, which could have an adverse impact on the adoption of TCAR. Finally, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, the interpretation of our or other clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition and results of operations. As physicians are influenced by guidelines issued by physician organizations, such as the **SVS Society for Vascular Surgery**, the rate of adoption of TCAR and sales of our products that facilitate the procedure are also influenced by medical society recommendations. We believe the **SVS Society for Vascular Surgery**'s Clinical Practice Guidelines, or SVS Guidelines, are of importance to the broader market acceptance of TCAR. The revised SVS Guidelines on the management of carotid artery disease were published in June 2021. Like previous versions of the guidelines, **it the revised SVS Guidelines** generally ~~discusses~~ **discuss** Carotid Artery Stenting, or CAS, and embolic protection methods, including flow reversal. The ~~2021 edition does~~ **revised SVS Guidelines do** state that TCAR is preferred over CEA and CAS in anatomically or physiologically high surgical risk patients, whether symptomatic or asymptomatic. If subsequent versions of the SVS Guidelines do not recommend TCAR, or if the **SVS Society for Vascular Surgery** issues a negative or more limited statement regarding TCAR, physicians may not adopt or continue to use TCAR or our products at the same rate or at all, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, if key opinion leaders who currently support TCAR cease to recommend TCAR or our products, our business, financial condition and results of operations will be adversely affected. Adoption of TCAR depends upon appropriate physician training, and inadequate training may lead to adverse patient outcomes, **adversely** affect adoption of TCAR and adversely affect our business. The success of TCAR depends in part on the skill of the physician performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our ENROUTE NPS and proper deployment of our ENROUTE stent. However, physicians rely on their previous medical training and experience when performing TCAR, and we cannot guarantee that all such physicians will have the necessary surgical and endovascular skills to perform the procedure. While we mandate physician attendance at our TCAR training program or training with proctors, we do not control which physicians perform TCAR or how much training they receive. Physicians who have not completed our training sessions may nonetheless attempt to perform TCAR. If physicians perform TCAR in a manner that is inconsistent with its labeled indications, with components that are not our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our and other clinical trials, studies or registries of TCAR. This result may negatively impact the perception of patient benefit and safety and limit adoption of TCAR and our products that facilitate the procedure, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, hospitals and physician organizations may adopt physician credentialing guidelines requiring TCAR training that is more extensive than our training program. If physicians conclude that we do not provide adequate TCAR training, they may be less likely to adopt TCAR and our products, which could have a material adverse effect on our business, financial condition and results of operations. Global supply chain constraints and constrained labor markets **have resulted and, including those caused by COVID-19, could continue to** result in the inability of our suppliers to deliver finished goods, components, sub-assemblies or materials to us on a timely basis or at all, **which would adversely affect our business, financial condition and results of operations**. We may not be able to maintain an adequate supply of the components, sub-assemblies and materials that are used to manufacture our TCAR products as well as to support our research and development activities for new products. For example, certain liners and shrink tubing components used in both the ENROUTE stent and the ENROUTE NPS have been in short supply and delivery of these materials have been delayed from time to time, which could result in manufacturing delays for our TCAR products. **In particular, we are concerned with the ability of a critical supplier of certain polymer tubing materials used in our products to provide us and our third party manufacturer these polymer tubing materials on a timely basis. If this supplier is unable to provide these polymer tubing materials on a timely basis, it could result in TCAR product delays to our customers, which, in turn, would adversely affect our results of operations.** Similarly, we rely on Lake Region Medical for our supply of guidewires, **Nordson Medical for our balloon catheters, and Galt Medical for our transcatheter access kits**, which have also been in short supply from time to time. If there were a shortage of supply, the cost of components, sub-assemblies and materials may increase or we may need to pay a premium to obtain sufficient supply, either of which could harm our ability to provide our products on a cost-effective basis or at all, or we may experience delays in providing our TCAR products to our customers. We also may experience delays in and increased costs for our research and development programs and clinical trials due to the inability to obtain the necessary materials to advance these programs and trials. In connection with any supply shortages, reliable and cost-effective replacement sources may not be available on short notice or at all, and this may force us to increase prices and face a corresponding decrease in demand for our TCAR products, or force us to absorb these increased costs. Our suppliers may also be impacted by supply or labor shortages which may delay or impact the availability of the components, sub-assemblies and materials needed to manufacture our TCAR products. In the event that any of our suppliers experience supply or labor shortages, delays, or were to reduce, or discontinue, production of our key product components, sub-assemblies or the materials used in our TCAR products, developing alternate sources of supply for these items would be time consuming, difficult and costly. If we or one of our suppliers were to experience

a supply shortage with our components, sub- assemblies and the materials or labor necessary to manufacture our TCAR products our reputation in the market, demand for our TCAR products and our operating results may be significantly and adversely affected and new products may be delayed. **We rely on Cordis** to supply the ENROUTE stent, and if Cordis fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations. We rely on Cordis to manufacture the ENROUTE stent pursuant to a supply agreement, **and as such, Cordis is our sole supplier of this product**. ~~We~~ **While we** strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, **and no assurance can be provided that this strategy will be sufficient. If we were to experience a shortfall or issue with the supply of ENROUTE stents by Cordis,** we estimate that it would take up to two years or more to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for a different carotid stent. In addition, Cordis currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. This facility has previously and in the future could become subject to a COVID- 19 **or other** outbreak which would cause Cordis to temporarily shut down manufacturing operations, which would in turn present risk to the ongoing supply of our stents used in TCAR procedures. If Cordis ^L's ability to manufacture the ENROUTE stent is interrupted as a result **or for any other reason, including, for example, its inability to obtain necessary or sufficient components or products from other third parties**, or if Cordis experiences a product recall, **cash flow or liquidity issues** or breaches its supply agreement with us, we may not have a sufficient number of stents for delivery to support TCAR procedures. ~~Finally, if not extended, our supply agreement with Cordis will terminate when our license agreement with Cordis terminates and we can provide no assurance that we will be able to negotiate or enter into a new supply agreement with Cordis on terms that are acceptable to us, or at all. We or Cordis may wish to re-evaluate certain aspects of the supply agreement we have with Cordis which may lead to lengthy or costly negotiations and affect our ability to obtain the ENROUTE stent at an acceptable price or at all.~~ Any shortfall in the supply of ENROUTE stents may result in lower adoption rates for TCAR, fewer TCAR procedures being performed **generally, and a material adverse effect on our business, financial condition and results of operations.** General macroeconomic factors, including inflation, price pressures, and ~~the~~ **recessionary risk risks of a recession**, could increase our manufacturing costs and operating expenses or lower demand for our TCAR products and have a material adverse impact on our financial condition and results of operations. The risk of a sustained economic downturn or recession and other macroeconomic ~~phenomena-factors~~ **could adversely affect customer demand for our TCAR products, or otherwise have an adverse impact on our results of operations and financial condition**. We continuously monitor the effects of inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, which may adversely affect our results of operations. Specifically, we are experiencing inflationary and price pressures and increased labor costs and labor and staffing shortages, affecting the cost of the components for our TCAR products and the wages that we pay our employees, as well as the wages our vendors pay their employees, due to challenging labor market conditions. Competitive, macroeconomic and regulatory conditions restrict our ability to fully recover, such as increased costs through price increases, higher costs of acquired goods and services resulting from inflation, other drivers of cost increases or reduced demand for TCAR products. We may be unable to pass these increased costs along to our customers or fully offset the impact of persistent inflation or a recession. Our inability or failure to do so could have a material adverse effect on our business, financial condition and results of operations or cause us to need to obtain additional capital earlier than anticipated. **General macroeconomic factors also may affect our customers, vendors and suppliers and their ability to pay us or continue to supply us products and services, which could also adversely affect our results of operations or financial condition**. If we are not able to obtain or maintain adequate levels of third- party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or if patients are left with significant out- of- pocket costs, it would have a material adverse effect on our business, financial condition and results of operations. TCAR is currently covered under certain circumstances for certain patients by the Centers for Medicare and Medicaid Services, or CMS, under a National Coverage Determination, ~~or NCD~~, and has been covered by some commercial payers, independent networks and other entities not governed by the National Coverage Determination. In the United States, we derive our revenue from sales to hospitals and medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third- party payers, including Medicare, Medicaid, Veterans' Administration, private commercial insurance companies, health maintenance organizations and other healthcare- related organizations, and then bill patients for any applicable deductibles or co- payments. For example, our contracts are with the hospitals and medical centers that purchase our products for use with TCAR and not with the commercial payers. As a result, access to adequate coverage and reimbursement for our products by third- party payers is essential to the acceptance of our products by our customers. However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third- party payers, so coverage and reimbursement can differ significantly from payer to payer, and each coverage decision and level of reimbursement is independent. As a result, third- party reimbursement may not be available or adequate for our products, and there is no guarantee that we will be able to maintain our current levels of coverage or reimbursement or be able to expand coverage to other insurance carriers. Further, payers continually review new technologies for possible coverage and can, without notice, deny or limit coverage for products and procedures or delay coverage approval until further clinical data are available. As a result, the coverage determination, technology assessment, and coverage reconsideration processes are often time- consuming and costly processes that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. If third- party reimbursement is not available or adequate for TCAR procedures using our products, or if there is any decline in the amount that payers are willing to reimburse our customers for TCAR, new customers may not adopt, or may reduce their rate of adoption of, our products and we could experience additional pricing pressure, any of which could have a material adverse effect on our business, financial condition and results of operations. Products for carotid stenting including our TCAR products are covered for Medicare beneficiaries under certain circumstances

under an NCD 20.7 for Percutaneous Transluminal Angioplasty. Coverage for non-Medicare patients depends upon commercial and other payer policies. Based on reimbursement information regarding CAS from IBM® MarketScan® Inpatient View, we estimate that approximately 75% of carotid procedures are reimbursed by CMS and the remaining approximately 25% are reimbursed by commercial and other payers. The Medicare program is administered by CMS and the Medicare Administrative Contractors, or MACs, which make determinations regarding Medicare hospital and physician coverage and payment. CMS reimburses hospital inpatient services based on Medicare Severity Diagnosis Related Groups, or MS-DRGs. All CAS, TCAR and CEA procedures are currently paid only as Medicare inpatient procedures. CMS's policy focus on hospital price transparency, site (e.g. inpatient, outpatient, ambulatory surgery center and office) neutral payments and MS-DRG refinements may place additional downward pressure on future hospital inpatient payments. Medicare payments to physicians are based on a Resource Based Relative Value System. CMS's policy changes to adjust or reallocate reimbursement between primary care services and specialty services may result in reductions in the payment rate for procedures involving our products. As a result of any reductions in payments to hospitals and physicians for TCAR procedures, TCAR utilization may decline, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, patients may elect to reduce or defer out-of-pocket costs during times of economic uncertainty or periods of legislative change. If hospital, physician and / or patient demand for TCAR, and thus our products that facilitate the procedure, are adversely affected by third-party reimbursement policies and decisions, it will have a material adverse effect on our business, financial condition and results of operations. **CMS released Any future reconsideration of the applicable Medicare final decision update to NCD 20.7, Percutaneous Transluminal Angioplasty could result in expansion- expanding of the Medicare coverage of carotid artery stenting procedures including TCAR based on. CMS determined that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a FDA approved carotid stent with a FDA-approved indications or cleared embolic protection continued or additional coverage limitations, including a requirement to participate in CMS-approved investigational studies. CMS's NCD that covers TCAR and CAS is subject to change based upon the availability of new trial data and other clinical data as well as the development and availability of new medical devices- device and medical procedures in this space- for Medicare beneficiaries in including the medical community's current understanding of patient patients with selection and operator experience and their impact on periprocedural complications, among other factors that can impact patient outcomes. In particular, the comparative benefits of various revascularization procedures and medical devices to prevent future strokes in symptomatic and asymptomatic carotid stenosis patients as well as ways to optimize patient outcomes are subject to ongoing and continuous review and clinical evaluation. For example, in January 2023, CMS accepted a formal request from the Multispecialty Carotid Alliance to expand Medicare beneficiary access for carotid artery stenting with embolic protection stenosis ≥ 50% and in patients at high risk and standard risk for CEA with asymptomatic carotid artery stenosis ≥ 70% under the following conditions: (1) Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and symptomatic after CAS. (2) First-line evaluation of carotid artery stenosis ≥ 50% must use duplex ultrasound. (3) Computed-tomography angiography (CTA) or magnetic resonance angiography (MRA) if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra-cranial circulation. (4) Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results or contraindicated for CTA or MRA. Prior to furnishing CAS, the practitioner must engage in a shared decision-making interaction with the beneficiary. The shared decision-making interaction must include: (1) Discussion of all treatment options for carotid stenosis including the removal of facility or operator requirements. We submitted comments to CMS prior to the initial 30-day public comment period on the NCD closing on February 11, carotid endarterectomy (CEA) 2023. Submitted comments are available on the CMS website. The proposed decision memo is due July 12, CAS (which includes TCAR) 2023 with a public comment period ending on August 11, and optimal 2023. The national coverage analysis completion date is expected in the fourth quarter of 2023. To the extent the medical community therapy (OMT). (2) Explanation of risks and benefits for each option specific to the beneficiary's or CMS clinical condition. (3) Integration of clinical guidelines (e.g., patient co-morbidities and concomitant treatments). (4) Discussion and incorporation of beneficiary's views change regarding personal preferences and priorities in choosing a treatment plan. Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. While we believe the revised NCD 20.7 will benefit carotid artery disease awareness in general and help grow the overall carotid intervention market, which would be a potential positive for all carotid interventions, including TCAR, CAS and CEA procedures, either individually or in comparison to each other, on issues of safety and effectiveness, operator experience, or patient selection or qualifications for coverage and reimbursement under the NCD, the demand for our TCAR products could be materially impacted. Therefore, we can provide no assurance can be provided that the level of coverage and reimbursement this will prove true. In addition, market share and demand, and / or revenues while we believe the higher associated procedural stroke risk for any of our products transfemoral carotid artery stenting and steep learning curve will continue to limit the pool of eligible patients and skilled interventionalists, thereby limiting the growth potential for transfemoral CAS in the near term, no assurance can be maintained provided that this will prove true either.** Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and

reimbursement are not available for TCAR or our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected. Additionally, when payers combine their operations, the combined company may elect to reimburse for TCAR at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payers participating in the consolidation does not reimburse for TCAR at all, the combined company may elect not to reimburse for TCAR, which would adversely impact our business, financial condition and results of operations. If we fail to comply with our obligations in our intellectual property license from Cordis, we could lose license rights that are important to our business. We are a party to a license agreement with Cordis, under which Cordis has granted us a worldwide, non- exclusive, **perpetual**, royalty- bearing license, without the right to sublicense, to certain of its intellectual property related to the PRECISE ® carotid stent for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. ~~In August 2021, Cardinal Health sold Cordis to private equity firm Hellman & Friedman LLC.~~ Our license agreement with Cordis imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Cordis, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. ~~If not extended, this license will expire on a country- by- country basis upon the expiration of all applicable Cordis patents — in certain countries, for example, our rights are expected to expire within the next few years.~~ Termination of this license for failure to comply with such obligations or for other reasons, or reduction, elimination or expiration of our licensed rights under it or any other license or agreement, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into new licenses for different stents. The occurrence of such events could materially harm our business and financial condition. The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in- license, and any failure by us or our licensors, including Cordis, to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. **We rely on Cordis to supply....., 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. Risks of using our products in TCAR include risks that are common to surgical and endovascular procedures and are detailed in the FDA- approved and FDA- cleared labeling. Major adverse events associated with all carotid interventions include stroke, heart attack and death. These risks may prevent widespread market adoption in the absence of adequate physician training on our products and in appropriate patient selection. Our current products are contraindicated, and therefore should not be used, in certain patients. Our ENROUTE NPS is contraindicated in patients in whom antiplatelet and / or anticoagulation therapy is contraindicated; patients with uncorrected bleeding disorders; patients with severe disease of the ipsilateral common carotid artery; and patients with uncontrollable intolerance to flow reversal. Our ENROUTE stent is contraindicated in patients in whom antiplatelet and / or anticoagulation therapy is contraindicated; patients in whom the ENROUTE NPS is unable to be placed; patients with uncorrected bleeding disorders; patients with known allergies to nitinol; and patients with lesions in the ostium of the common carotid artery. Our ENHANCE peripheral access kit is contraindicated in patients with a known or suspected obstruction in the vessel. Our ENROUTE guidewire is contraindicated in patients judged not acceptable for percutaneous intervention. Our ENROUTE Enflate RX Balloon ~~Dilation~~ **Dilatation** Catheter is contraindicated for use in coronary arteries. Generally, further contraindications include, but may not be limited to: patients with highly calcified lesions resistant to PTA; patients with a target lesion with a large amount of adjacent acute or sub- acute thrombus; patients with uncorrected bleeding disorders; and patients that have not been anti- coagulated. Additionally, patients who lack at least five centimeters of common carotid artery free of significant disease are not indicated for our ENROUTE NPS. We face manufacturing risks that could adversely affect our ability to manufacture products, reduce our gross margins and negatively affect our business and operating results. Our business strategy depends on our ability to manufacture, and our contract manufacturers' ability to manufacture, our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have facilities located in Sunnyvale, California, and in Plymouth, Minnesota, where we currently assemble and package certain of our products, and inspect, release and ship all of our products. If our or our manufacturing partners' facilities suffers damage, or a force majeure event, this could materially impact our ability to operate. We are also subject to numerous other risks relating to our manufacturing capabilities, including: • Quality and reliability of components, sub- assemblies and materials that we source from third- party suppliers, who are required to meet our quality specifications, the majority of which are our single- source suppliers for the products they supply; • Our or our manufacturing partners' inability to secure components, sub- assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms; • Our or our manufacturing partners' inability to maintain compliance with quality system requirements or pass regulatory quality inspections; • Our or our manufacturing partners' failure to develop products in a timely manner or to required specifications or to increase production capacity or volumes to meet demand; • Our or our manufacturing partners' inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and • Difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner. As demand for our products increases, we will have to invest additional resources to purchase

components, sub- assemblies and materials, hire and train employees, and enhance our manufacturing processes. If we or our manufacturing partners fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations, and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub- assemblies and materials with our existing products, the manufacture of these products may require modification of our or our manufacturing partners' current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub- assemblies and materials or the development of new manufacturing technologies. It may not be possible for us or our manufacturing partners to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current gross margins, all of which could have a material adverse effect on our business, financial condition and results of operations. We depend on a limited number of single- source suppliers to manufacture our components, sub- assemblies, materials and products, including Cordis, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations. We rely on single- source suppliers for the components, sub- assemblies and materials for our products, such as our ENROUTE stent and for ~~the certain~~ key components, sub- assemblies and materials for our ENROUTE NPS. ~~For example~~ **In addition**, we rely on Lake Region Medical to supply our guidewires, **Nordson Medical for our balloon catheters, and Galt Medical for our transcatheter aortic valve replacement kits**. These components, sub- assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub- assemblies and materials, and we do not carry a significant inventory for some of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses. Our manufacturing partners, **including Cordis**, rely on single- source suppliers as well, and are subject to the foregoing risks. Our and our manufacturing partners' dependence on third- party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, **financial condition and results of operations**, including: • Interruption of supply resulting from modifications to, or discontinuation of, a supplier' s operations; • Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier' s failure to produce components that consistently meet our quality specifications; • Price fluctuations due to a lack of long- term supply arrangements with our suppliers for key components; • Inability to obtain adequate supply in a timely manner or on commercially reasonable terms due to global supply chain constraints or other factors; • Difficulty identifying and qualifying alternative suppliers for components in a timely manner; • Inability of suppliers to comply with applicable provisions of the FDA' s Quality System Regulation, or QSR, or other applicable laws or regulations enforced by the FDA and other state and applicable regulatory authorities; • Inability to adequately ensure the quality of products and components manufactured by third parties; • Production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications; • Delays in delivery by our suppliers due to changes in demand from us or their other customers; **• Delays or inability of suppliers to provide products and components due to cash flow or liquidity issues**; and • An outbreak of disease or similar public health threat, such as the ongoing threat of new COVID- 19 variants, particularly as it may impact our supply chain. Although we require our third- party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcatheter Aortic Valve Replacement System, manufactured by Cordis. Our decision to recall these lots was based on complaints we received about tips detaching from the stent delivery system as well as internal testing that we conducted. We determined the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, have to purchase replacement products, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted. We face risks related to health **pandemics**, epidemics and other outbreaks, such as ~~the~~ COVID- 19 **pandemic** and ~~its the spread of new~~ variants, which may negatively impact our business and operations. Our business **has been in the past and in the future** could be adversely impacted by the effects of health **pandemics**, epidemics and other outbreaks, such as ~~the~~ COVID- 19 **pandemic** and ~~its the spread of new~~ variants, or COVID- 19, including through: • Postponement of TCAR procedures by physicians or their patients in response to COVID- 19 or the diversion of resources to treat patients with ~~COVID- 19 or other~~ conditions deemed higher priority; • Hospital staffing shortages which may result in fewer diagnoses and a lower number of TCAR procedures performed; • Restrictions on hospital capacity, or other resource constraints, such as the availability of contrast dye, that may cause problems for hospitals scheduling or rescheduling TCAR procedures; • Limitations in hospital or employee resources that would otherwise be focused on performing TCAR procedures; • Patients who may be reluctant to visit their physicians at their offices or in hospitals ~~due to fear of contracting COVID- 19~~; • Physicians not performing as many diagnostic tests for their patients and closures, staffing shortages, or reduced hours of the labs where these tests are performed, ~~even where physicians continue to treat symptomatic patients, treatment of asymptomatic patients is being deferred in many cases in areas where COVID- 19 cases and hospitalizations are significant, which has may translated~~ **translate** into fewer than expected TCAR procedures being performed throughout various periods of the pandemic; • Delays in

enrollment in **our** clinical trials across the medical device industry which may affect any new trials we are pursuing or decide to pursue, including our ROADSTER 3 trial, which is related to our standard surgical risk post-approval study, and our Neuroprotection in Transcatheter Aortic Valve Replacement, or NITRE-1, trial, which is related to one of our stroke treatment products under development; • Governmental mandates related to COVID-19 or other infectious diseases, which have impacted, may continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and / or reduce our margins. An extended implementation of governmental mandates could impact our ability to operate effectively and conduct ongoing manufacturing or research and development activities. However, we are considered an essential business under applicable state rules and our manufacturing operations to date are ongoing; • Delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees; • **Our Unavailability of** key personnel or large groups of our employees **due** contracting a virus, such as COVID-19. We have taken steps to provide for our employees, including providing the ability for employees to work remotely and **an outbreak** implementing strategies to support a safe work environment for onsite employees. In addition, we have required our employees to receive the COVID-19 vaccine and implemented distancing policies and protocols established to continue manufacturing and other operations; • Intermittent travel restrictions and restrictive hospital policies impacting our sales professionals and therapy development specialists who support them; • Competition for operating room and hybrid operating rooms within hospitals that are resource constrained or have dedicated certain resources only to **outbreak** COVID-19 patients; • The spread of new virus variants and varying infection and related hospitalization rates which increase the volatility and uncertainty in the expected number of TCAR procedures and demand for our products; • Hospitals cancelling and deferring elective surgeries, which reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as they seek cost savings; • Hospitals having issues with cash flow or ceasing doing business due to the impact of **the pandemic** COVID-19 on their operations, which could reduce the number of hospitals where TCAR is performed and adversely affect our ability to collect amounts due to us and our revenue as a result; • The **effect of an** outbreak **on** and persistence of COVID-19 in international markets that we have targeted for our **anticipated** international expansion has also delayed preparation for **or** and launch of such expansion efforts; • Delayed regulatory timelines for approval **approvals** in some countries; • Prolonging existing restrictions related to COVID-19 that have impacted the number of TCAR procedures performed; • Hospitals restricting or limiting access for non-patients, including our sales professionals and therapy development specialists, **or our sales personnel choosing not to enter hospitals**, which has **could** negatively impacted **impact** our access to physicians and their staff; or • Members of our field team may choose not to enter hospitals due to preexisting conditions, personal choice, or on doctors' orders or may be unable to enter hospitals due to hospital policy, although they continue to be available to support TCAR procedures, either in person or virtually. The extent to which COVID-19 impacts our business will depend on future developments, which are uncertain and cannot be predicted, including indirect impacts on the labor market and the operations of our business as well as the operations of our contractors, partners, and our customers. Additionally, President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations is unclear. The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business. We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, **violence**, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business. Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our manufacturing partners and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products would be negatively affected by many factors, including our rapid growth, product recalls, pandemics, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters **and**, weakening of economic conditions or consumer confidence **and the realization of other risks as described in this section** **future economic conditions**. Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements **and our manufacturing may be affected by the impact of COVID-19 and other macroeconomic forces on our suppliers. We are working to increase our inventory on hand in reaction to global supply chain constraints, but these inventory levels may prove to be inadequate**. If we do not have adequate supply of components, sub-assemblies and materials there may be interruptions, delays or cancellations of deliveries of our TCAR products to our customers, any of which would damage our reputation, customer relationships and

business. In addition, several components, sub- assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations. Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business. Our quarterly and annual results of operations, including our revenue, net income or net loss and cash flow, may vary significantly in the future, and period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period- to- period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

. Our actual operating results have differed in the past, and in the future may differ, significantly from our guidance and / or analyst expectations, which has caused in the past and could again cause in the future the market price of our common stock to decline. From time to time, we release guidance regarding our future performance, such as our anticipated annual revenue, that represents our management' s estimates as of the date of release. This guidance, which consists of forward- looking statements, is prepared by our management and is qualified by, and subject to, the assumptions and the other information contained or referred to in the release. Our guidance is not prepared with a view toward compliance with published guidelines of the American Institute of Certified Public Accountants, and neither any independent registered public accounting firm nor any other independent expert or outside party compiles, examines or reviews the guidance and, accordingly, no such person expresses any opinion or any other form of assurance with respect thereto. Our guidance is based upon a number of assumptions and estimates that, while presented with numerical specificity, is inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. We generally state possible outcomes as high and low ranges which are intended to provide a sensitivity analysis as variables are changed but are not intended to represent that actual results could not fall outside of these ranges. The principal reason that we release this data is to provide a basis for our management to discuss our business outlook with analysts and investors. Analysts and others also publish financial projections or forecasts from time to time. We do not accept any responsibility for any projections or reports published by any such persons. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions of the guidance furnished by us will not materialize or will vary significantly from actual results.

Accordingly, our guidance is only an estimate of what management believes is realizable as of the date of release. Actual results will vary from the guidance and the variations may be material. Investors should also recognize that the reliability of any forecasted financial data will diminish the farther in the future that the data are forecast. In light of the foregoing, investors are urged to put the guidance in context and not to place undue reliance on it. Any failure to successfully implement our operating strategy or the occurrence of any of the events or circumstances set forth in this Annual Report on Form 10- K could result in the actual operating results being different than our guidance, and such differences may be adverse and material. The failure to achieve such guidance has in the past disappointed and in the future could disappoint investors and analysts and cause the market price of our common stock to decline. While we do not provide quarterly revenue guidance, we lowered our annual revenue guidance in connection with the release of our preliminary third quarter 2023 revenue results in October 2023, which contributed to a significant decrease in our stock price, which has decreased from a 52- week high of \$ 58. 04 on January 13, 2023 to a 52- week low of \$ 6. 08 on October 26, 2023.

We have a limited total addressable market based on our current labeling restrictions. The total addressable market for TCAR is limited by a number of factors. The safety and effectiveness of certain products for TCAR has not been established for certain patients. For example, the FDA- cleared labeling for the ENROUTE NPS states that patients should have at least five centimeters of common carotid artery free of significant disease for initial access to the artery and positioning of the ENROUTE NPS sheath. In addition, per the FDA- approved labeling for the ENROUTE stent, TCAR is limited to certain threshold degrees of stenosis depending on symptom and surgical risk status. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions or severe vessel tortuosity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market. Expanding the addressable market for TCAR is dependent upon reimbursement expansion initiatives, favorable data from any post- approval study we or other researchers conduct, and obtaining and maintaining coverage and adequate reimbursement for any new product approvals. In May 2022, we announced FDA approval of a label expansion for the ENROUTE stent for use in standard surgical risk patients. In June 2022, we announced that CMS, through collaboration with the SVS Society for Vascular Surgery' s Patient Safety Organization and their Vascular Quality Initiative, or VQI, has expanded coverage for TCAR to include standard surgical risk patients within the VQI' s TCAR Surveillance Project. As a condition of FDA approval for such label expansion, we are conducting **and currently enrolling patients in** a prospective, multi- center, single- arm post- approval study, ROADSTER 3, to assess real- world treatment of standard surgical risk patients with carotid artery disease using TCAR **and announced enrollment of our first patient in September 2022.** If the ROADSTER 3 study or other studies conducted by independent researchers or organizations, or complaints or other reports from our customers or patients, reveal a higher rate of adverse events or other unexpected safety or efficacy concerns, FDA may restrict or withdraw the label expansion approval. Any future report or publication raising any material safety or efficacy concerns regarding any of our approved products or approved uses may cause CMS or other payors to modify or restrict their coverage and reimbursement

policies for our products and related procedures. If any of these events were to occur, or if we fail to demonstrate continued safety and efficacy for our approved products and their indications, it may have a material adverse effect on our business, financial condition and results of operations. Changes in public health insurance coverage and government reimbursement rates for the TCAR procedures using our products could affect the adoption of our products and our future revenue. The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third- party reimbursement. Even if we succeed in bringing our products to market in ~~additional~~ foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices. Cost- containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability. In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups reduces market prices for our products and / or require administrative fees, thereby reducing our revenue and / or margins. While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue. We may not be able to achieve or maintain satisfactory pricing and margins for our products. Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for TCAR could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. **In addition, the introduction of competitive stents that could be used in TCAR procedures and other products could also put pressure on the pricing of our products.** If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations. **Also, our use of distributors in non- U. S. countries may adversely impact our gross margins.** If we are required to vacate a facility, we may be unable to produce the products we manufacture or we may experience delays in production or an increase in costs, which could adversely affect our results of operations. We currently maintain a portion of our manufacturing, **warehouse**, research and development and non- field- based sales, general and administrative operations in a building located in Sunnyvale, California, which is situated on or near earthquake fault lines. We have redundant manufacturing for our ENROUTE NPS at our Plymouth, Minnesota facility. Should either of our ~~buildings~~ **facilities** be significantly damaged or destroyed by natural or man- made disasters, such as earthquakes, fires, **tornados** or other events, including climate change- related severe weather or disasters, it could take extensive time to relocate or rebuild, during which time our employees may seek other positions and our research and development would cease or be delayed. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage, losses caused by earthquakes, losses we may suffer due to our products being replaced by competitors' products or loss in value due to associated decreases in our stock price. The inability to perform our research and development activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facilities could have a material adverse effect on our business, financial condition and results of operations. **Furthermore, the lease for our Sunnyvale, California manufacturing facility, which contains a renewal option for a five- year lease extension, currently expires in October 2024. 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.** In addition, we rely on our manufacturing partners to supply certain of our products, and our partners are subject to similar risks with respect to their facilities. If our manufacturing partners' facilities are damaged or destroyed and their ability to supply products to us is limited, it could negatively affect our reputation, physician relationships and TCAR adoption, all of which could have a material adverse effect on our business, financial condition and results of operations. Several of our products are sterilized at a particular third- party facility, with limited alternate facilities. If an event occurs that results in damage to or closure of one or more of such facilities, we may be unable to sterilize such products at the previous levels or at all. Because of the time required to approve and license a sterilization facility,

a third party may not be available on a timely basis to replace capacity in the event sterilization capacity is lost. If we fail in our sales training initiatives, to increase or improve our sales and marketing capabilities or to develop broad brand awareness, our growth will be impeded and our business will suffer. We currently rely on our direct sales force to sell our products in targeted geographic regions in the U. S., and any failure to continue to hire, train, maintain, motivate and grow our direct sales force could harm our business. **Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales force fails to adequately promote, market and sell our products, our revenue may suffer.** The members of our direct sales force are highly trained and possess substantial technical and clinical expertise, which we believe is critical in driving adoption of TCAR. The members of our U. S. sales force are at-will employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical and clinical expertise and qualifications, or if we are unable to successfully instill such technical and clinical expertise in replacement personnel, our revenues and results of operations could be materially harmed. **Because the competition for qualified sales personnel is high, we cannot assure you we will be able to hire and retain sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which could have an adverse impact on our business. In addition, the hiring and training of new sales personnel takes time and could adversely affect our revenue and financial results for a particular period, as could changes in our sales territories and sales structure. In addition, we have expanded our sales and marketing infrastructure, including number of sales personnel and sales territories, to help us drive and support revenue growth and we intend to continue this expansion. These changes naturally result in some sales disruption, which disruption adversely affected our revenue in various periods throughout 2023 and may continue to adversely affect our revenue through the first half of 2024.** In order to generate future growth, we plan to continue to expand and leverage our sales, marketing, and medical affairs infrastructure to increase our trained physician and hospital customer base and our business. Identifying and recruiting qualified sales, marketing and medical affairs personnel and training them on TCAR, on applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. **There is significant competition for direct sales personnel with strong sales skills and clinical knowledge and it** often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. **In addition, the loss of key sales personnel could impact our physician and customer relationships and future ability to sell to certain accounts covered by such personnel.** Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations. **Our** medical affairs department may not train physicians at a rate sufficient to expand our physician base in a manner consistent with our business plan. Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand is critical to achieving broad acceptance of our products and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products. The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments or products that are safer, more effective or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated. Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. **Competition in our industry has increased with new technologies and market entrants seeking approvals for carotid disease treatment indications in the U. S.** CEA has historically been performed by vascular surgeons as the primary surgical solution for carotid artery disease. The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Inc., Getinge AB/Maqet, Baxter International Inc., Terumo Medical Corporation, W. L. Gore and Associates, Inc. and Edwards Lifesciences Corporation. Some competitors market products for use in CAS, such as peripheral access kits, stents, distal and proximal embolic protection devices, guidewires, balloons and sheaths. Such companies include Abbott Laboratories, Boston Scientific Corporation, Cook Medical Inc., Cordis Corporation, Medtronic plc, Terumo Medical Corporation, W. L. Gore and Associates, Inc., Contego Medical Inc. and InspireMD, Inc. **Preliminary results from Contego Medical Inc.' s PERFORMANCE II and InspireMD, Inc.' s C- Guardians IDE studies were presented at the VIVA conference in November 2023. Abbott Laboratories, Contego Medical Inc. and InspireMD, Inc. have also announced plans to develop products for TCAR.** These technologies, other products that are in ongoing clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance. **In addition, physicians may choose to use other company stents and not our ENROUTE stent in connection with TCAR procedures, including a recently approved stent by Abbott Laboratories, or may choose to use products not labeled for TCAR in an off label fashion and competitive companies may promote their CAS products for off- label use in TCAR.** We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating

results. These companies enjoy several competitive advantages, including: • Greater financial and human capital resources; • Significantly greater name recognition; • Established relationships with vascular surgeons and other treating specialties, referring physicians, customers and third- party payers; • Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and • Established sales, marketing and worldwide distribution networks. Because of the size of the market opportunity for the treatment of carotid artery disease, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New treatment options may be developed that could compete more effectively with our products due to the prevalence of carotid artery disease and the extensive research efforts and technological progress that exist within the market. **This is particularly true in light of the revised NCD 20. 7 – Percutaneous Transluminal Angioplasty, which expanded reimbursement coverage of transfemoral carotid artery stenting into asymptomatic and standard surgical risk patients and could lead to increased future competition for our TCAR products.** Our ability to compete depends on our ability to innovate successfully and deliver any new products in a timely manner. The market for our products is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop **and introduce** products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' **products. Developing products is expensive and time- consuming and could divert management' s attention away from our core TCAR products. However, if we are unsuccessful in developing and commercializing new products, our ability to increase our revenue may be impaired. Even if we are successful in developing additional products, the success of any new product offering or enhancements to existing products will depend on several factors, including our ability to: • properly identify and anticipate physician and patient needs; • develop and introduce new products or product enhancements in a timely but controlled manner; • avoid infringing upon the intellectual property rights of third- parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials; • obtain the necessary regulatory clearances or approvals for new products or product enhancements; • be fully FDA- compliant with marketing of new devices or modified products; • provide adequate training to potential users of our products; • obtain adequate coverage and reimbursement for our customers performing procedures using our products; and • develop an effective and dedicated sales and marketing team for any new** products. We are currently focused on improving existing products for TCAR, developing new products for TCAR, and developing new products for other disease states beyond carotid artery disease. For example, following receipt of 510 (k) clearance from the FDA in September 2022, we initiated a limited market release of our ENROUTE Enflate Transcarotid RX Balloon **Dilation-Dilatation** Catheter in the fourth quarter of 2022 **and a full market release during the second quarter of 2023. In addition, we received PMA approval for tapered configurations of our ENROUTE stent in June 2023 and initiated a limited market release in the first quarter of 2024** with a full market release planned in **the first half of 2023-2024**. If we are unable **to continue** to develop new products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business. Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations. **In addition, the launch of new products if not timed correctly and if not controlled properly may result in an adverse impact on sales of such new products, as well as sales of our TCAR products. In addition, our new products may not carry the same margins as our current TCAR products, which could adversely affect our gross margins**. Defects or failures associated with our products could lead to additional recalls, safety alerts or litigation, as well as significant costs and negative publicity. Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off- label uses or inadequate disclosure of product- related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and could have a material adverse effect on our business, financial condition and results of operations. We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate. The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of

the neck with the brain as the end organ is dangerous and presents risks of adverse events such as bleeding, arterial dissection, cranial nerve injury, myocardial infarction, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations. Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals. We are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. The failure of TCAR to meet patient expectations or the occurrence of adverse events from TCAR could impair our financial performance. Our future success depends upon patients having an experience with TCAR that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as arterial restenosis or dissection, cranial nerve injury, wound complications, transient ischemic attacks, stroke, heart attack, and death. If the results of TCAR do not meet the expectations of patients, or they experience adverse events, it could discourage patients from referring TCAR to others. For example, although we have not received any reports of strokes, deaths or other long-term patient sequelae from the tip detachments that triggered our recent recall, if there were to be patient injury, dissatisfied patients may express negative opinions through social media or we may otherwise suffer reputational damage or become subject to product liability lawsuits. Any failure to meet patient expectations and any resulting negative publicity or lawsuits could harm our reputation and future sales. **We depend on our failure to manage the transition associated with our Chief Executive Officer, retain our existing senior management team, and the loss of one or more key employees or an inability to attract and retain highly skilled employees qualified new personnel could harm have a material adverse effect on our business.** Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of **Erica Rogers, our new Chief Executive Officer, and Lucas Buchanan or CEO, Charles S. McKhann**, our Chief Financial Officer and Chief Operating Officer, **Lucas W. Buchanan, and our Chief Commercial Officer, Andrew S. Davis**, are essential to driving adoption of our products **and revenue growth**, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. **Mr. McKhann became CEO on November 2, 2023 succeeding Erica J. Rogers, who retired after having served as CEO and on our board of directors for over 11 years. Our failure to manage this CEO change and transition, retain our existing senior management team, or continue to attract and retain qualified new personnel could have a material adverse effect on our business.** In addition, the services of **Andrew Davis, CEO transition and any related uncertainty regarding our Chief Commercial Officer future business direction may be disruptive to our business and our relationships with employees and customers. Additionally, the departure of Ms. Rogers as our former CEO resulted in a loss of institutional knowledge and there can be no assurances that we will be able to mitigate that loss through our transitional consulting arrangement with her. If we are critical unable to driving execute an orderly transition, our business may be adversely affected. Furthermore, the success growth in sales of our business is dependent on the continuation of an experienced and talented management team. If we were to lose the benefit of the experience, efforts, and abilities of any of our key executives or products members of senior management, our business could be adversely affected. Any While we implemented retention packages for our key executives and employees during 2023, any of our employees may terminate their employment with us at any time and the recent significant decline in the value of long term incentives could also negatively impact our ability to retain key employees.** We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. In addition, our research and development programs, and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. We have

from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. When we hire employees from competitors or other companies, their former employers have previously and may in the future attempt to assert that these employees or we have breached legal obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment along with salary, benefits and other factors. If the perceived benefits of our stock awards decline, either because we are a public company, **the significant drop in our stock price during 2023** or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed. The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business. The ENROUTE stent has been approved by the FDA for the treatment of patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke, myocardial infarction and death, potentially leading to product liability claims. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing TCAR. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and / or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and / or enjoined several companies from engaging in off-label promotion. In addition, if our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by physicians, hospitals or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed. **Our past growth has provided, and our future growth may create, challenges to our organization. The number of our employees has increased significantly during the past several years and in the future, we expect to hire and train new personnel as we continue to grow and expand our operations.** Any growth that we experience in the future will require us to expand our sales, general and administrative personnel, manufacturing and distribution operations, and facilities and information technology, or IT, and infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed. As demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer. We may need substantial additional funding and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate our product development programs and commercialization efforts. We believe that our cash and cash equivalents and investments, together with our expected revenue, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including: • The degree and rate of market acceptance of TCAR and our products; • **The total market opportunity** ~~Whether we acquire third-party companies, products or~~ **for our products and our ability to penetrate and capture market share from other competing products and** technologies; • ~~Restructuring, refinancing-~~ **Our ability to continue to grow** ~~or our revenues~~ ~~repayment of debt and any default by the U. S. government~~ **maintain pricing and gross margins, especially in light of increased competition or investor perception thereof;** • **The effect of competing technologies and products** ~~on our business~~ ~~its debt which could have broad macroeconomic effects that could,~~ among

operating results and prospects, or other adverse market developments things, raise our borrowing costs; • The scope and timing of investment in **and the future success of** our sales force, marketing initiatives and physician training programs; • The scope, rate of progress and cost of our research and development activities, current or future clinical studies and additional regulatory clearances or approvals; • The scope and timing of investment in acute ischemic stroke and other neurovascular and cardiac products we may develop; • **The rate at which we expand internationally and our ability to launch and sell our products successfully in such markets; • Whether we acquire third- party companies, products or technologies; • Restructuring, refinancing or repayment of debt**; • The costs associated with any future product recall that may occur; • The costs of attaining, defending and enforcing our intellectual property rights; • **The impact of health epidemics and other outbreaks, such as the COVID-19 pandemic and the spread of new variants, on our business and operations**; • The emergence of competing technologies or other adverse market developments; and • **The rate at which we expand internationally impact of health pandemics, epidemics and other outbreaks, such as COVID-19 and its variants, on our business and operations**.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us. If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations. We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future. As of December 31, **2022-2023**, we had an aggregate of approximately \$ 75. 0 million in principal outstanding under our Loan Agreement with Oxford Finance. We must make significant interest- only monthly payments under the Loan Agreement, and the term loans outstanding under the Loan Agreement will begin to amortize in equal monthly installments beginning in July 2026 (unless we elect to extend the interest- only period by another year), which will divert resources from other activities. Our obligations under the Loan Agreement are collateralized by substantially all of our assets and we are subject to customary affirmative and negative covenants, including covenants limiting our ability and the ability of our subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type. The covenants related to the Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our Loan Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan Agreement to become immediately due and payable, termination of commitments to extend further credit, a 5 % increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. **Adverse developments with respect to the stability of financial institutions we do business with, or unstable banking, credit and / or capital market conditions generally, or the perception thereof, could adversely affect our ability to access cash, obtain additional financing, restructure or refinance our indebtedness, or meet our liquidity and debt service requirements. The recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure could materially and adversely affect our liquidity, financial condition, results of operations, business and stock price. Last year' s closures of Silicon Valley Bank, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC, has created bank- specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, and such access to date by us to our cash and cash equivalents held at SVB has been uninterrupted, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for**

our operations or delay our ability to access such funds. As of December 31, 2023, a portion of our cash and cash equivalents was maintained with SVB and exceeded federally insured limits. Substantially all of our cash equivalents and investments reside in a custodial account held by a third party, in which SVB Asset Management is the advisor. As of the issuance date of this Annual Report on Form 10-K, we have not experienced any losses on our deposits and all of our cash deposited with SVB has been accessible to us, although no assurance can be provided that we will not experience any future losses on our deposits or access to our cash equivalents and investments. As of December 31, 2023, our cash equivalents and investments are invested in highly rated money market funds, U. S. treasury bills, U. S. government securities, commercial paper, corporate bonds / notes, and agency bonds / notes. Uncertain financial markets, or a U. S. sovereign default or threat thereof, could result in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of securities in our investments could deteriorate and may have an adverse impact on the carrying value of these investments. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and / or custodial financial institutions. In the event we have a commercial relationship with a bank or lender that has failed or is otherwise distressed or if other banks and financial institutions enter receivership or become insolvent in the future, we may experience delays or other issues in accessing our cash and meeting our financial obligations. In addition, any future unstable banking, credit and / or capital market conditions could also adversely affect our ability to obtain additional financing, restructure or refinance our indebtedness, if needed, or meet our liquidity and debt service requirements or the ability of our suppliers, vendors, customers and others in which we do business to do any of the foregoing with respect to their respective businesses. We may acquire other companies or technologies, or enter into license agreements, distribution arrangements or strategic partnerships, which could fail to result in a commercial product or generate sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results. Although we currently have no agreements or commitments to complete any such transactions, we may in the future seek to acquire, license or invest in businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We could also seek to enter into distribution arrangements or strategic partnerships with third parties that we believe could increase our revenue or offer other commercial benefits. However, we cannot assure you that we would be able to successfully complete any acquisition, license agreement or distribution agreement we choose to pursue, or that we would be able to successfully integrate any business or product or technology in a cost-effective and non-disruptive manner. Similarly, we cannot guarantee that we would derive benefits from any distribution arrangement or other strategic partnership. The pursuit of potential acquisition, license or partnering opportunities may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable transactions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or strategic partners, or be successful in entering into an agreement with any particular target or partner, or obtain the expected benefits of any acquisition, license, investment or other strategic partnership arrangement. To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business, product or technology fails to meet our expectations, our operating results, business and financial condition may suffer. Our ability to utilize our net operating loss carryforwards may be limited. As of December 31, 2022-2023, we had U. S. federal and state net operating loss carryforwards, or NOLs, of \$ 320-332. +0 million and \$ 271-288. 5-6 million, respectively. Our U. S. federal NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2027 (U. S. federal NOLs, and certain state NOLs, arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028-2024. We may use these NOLs to offset taxable income for U. S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions may limit the NOLs we may use in any year for U. S. federal and state income tax purposes in the event of certain changes in ownership of our company. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We completed a 382 study of our historic ownership changes through December 31, 2023 and determined there are limitations currently in the process of performing a formal study to determine whether we experienced an ownership change during 2022 or in a prior taxable year. Pending the outcome of this study, we believe we may have experienced at least on "ownership change" in the past use of our loss and credit carryforwards 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, U. S. federal NOLs arising in tax years beginning after December 31, 2017 may only be used to offset 80 % of our taxable income. This change may require us to pay U. S. federal income taxes in future years despite generating a loss for U. S. federal income

tax purposes in prior years. Limitations under state law may differ. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers or patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. In the ordinary course of our business, we may become exposed to, or collect, store, or otherwise process sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store and process sensitive intellectual property and other proprietary business information. We rely on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and / or used by third parties or their vendors, to assist in conducting our business, and they also face numerous security threats. The ever-increasing use and evolution of technology, including cloud-based computing and artificial intelligence, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third party providers' systems, portable media or storage devices. Although we take measures designed to protect sensitive information from unauthorized access or disclosure, our IT and infrastructure, and that of our technology partners and third parties on which we rely, may be vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction-malfunctions, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by employees and / or other third parties, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks or the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We and the third parties on which we rely may be more susceptible to security breaches and other security incidents due to many of our employees and employees of our third-party service providers working remotely for some portion of time. Also, Russia's war with Ukraine may subject us and third-party service providers to heightened risks of cybersecurity incidents and security and privacy breaches, including attacks that could materially disrupt our research and development programs or other aspects of our operations. We continue to invest in leading-edge cybersecurity solutions, highly-qualified and certified security personnel and managed security services with respect to our data and IT in an effort to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to, or incidents or compromises impacting, our third-party providers' databases, systems, or other IT or infrastructure. Any system or other IT failure, accident or security breach or incident that causes interruptions in our own or in our third-party service providers' operations, or results in data loss, corruption, or unavailability, could result in a material disruption of our research and development programs or other aspects of our operations. In addition, if any disruption or security breach or incident results in loss, destruction, alteration, or unavailability of, or damage or unauthorized access to, our data or applications or unauthorized access to, disclosure, dissemination or other processing of confidential or proprietary information that we or our third-party service providers process, including personal information, we may incur liability as a result, our research and development programs and competitive position may be adversely affected. Any such disruption, failure or security breach or incident could also cause us to incur additional costs to respond to and otherwise address such disruption, failure or security breach or incident. In the event of any such disruption, failure or security breach or incident, or any perception that one has occurred, we could be exposed to claims, demands, and litigation from private parties, and governmental investigations and other proceedings and we could be subject to significant fines or penalties. **As a result of a new SEC rule on cybersecurity disclosure, we are required to disclose, on a current basis pursuant to new Item 1.05 of SEC Form 8-K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations.** We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and **no assurance** we may face increased costs and requirements to expend substantial resources in the event of an **can** actual or perceived security breach or incident **be provided that we will be successful in this regard**. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. **As In addition, our IT systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems. This enables us to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the IT needs associated with our evolving products. There can be no assurance that our efforts (including, but not limited to, consolidating, protecting, upgrading, and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology, including, but not limited to, generative artificial intelligence platforms) will be successful or that additional systems issues will not arise in the future. We have no experience selling our products outside of the United States and may be unsuccessful in achieving adoption of our products and revenue growth outside of the United States in a timely**

manner or at all. In addition, as international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial, legal and economic risks associated with doing business outside of the United States. Our long-term strategy is to sell our products outside the United States and increase our international presence. In furtherance of this strategy, we have taken actions to sell our products initially in Japan and China, including but not limited to, securing required regulatory approvals and, working towards obtaining reimbursement for our products, and entering into distribution agreements with distributors to sell our products in Japan and China. For example, once we commercially launch our products in the those countries. Our future sales in fourth quarter of 2022, we received approval from the Japan Association and China, as well as any other country, however, are dependent upon our ability to obtain adequate reimbursement for our products in the those Advancement of Medical Equipment countries. If we do not obtain adequate reimbursement for our ENROUTE NPS and ENROUTE stent. This strategy products in Japan or China or any other country, we may include establishing and maintaining physician outreach and education capabilities not be successful in selling our products in those countries. In addition, we have no experience selling our products outside of the United States and expanding therefore we may be unsuccessful in achieving adoption of our products and revenue growth outside of the United States in a timely manner our or at all relationships with international distributors, providers and payers.

Furthermore, Doing doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations and increases in infrastructure costs including legal, tax, accounting and information technology;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for or enforcing or defending our intellectual property rights in some countries;
- Obtaining regulatory clearance where required for our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with obtaining and maintaining adequate reimbursement for our products and managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Difficulties in finding effective and adequately training and managing international distributors;
- Difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established;
- Training of third parties on our products and the procedures in which they are used;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- The imposition of additional U. S. and foreign governmental controls or regulations; new or enhanced trade restrictions and restrictions on the activities of foreign agents, representatives, and distributors; withdrawal from or revision to international trade agreements and the imposition or increases in import and export licensing and other compliance requirements, customs duties and tariffs, import and export quotas and other trade restrictions, license obligations, and other non-tariff barriers to trade;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;
- Fluctuations in our operating performance based on our geographic mix of sales;
- Transportation delays and interruptions;
- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U. K. Bribery Act of 2010 and comparable laws and regulations in other countries. Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations. Additionally, pursuant to the terms of our existing intellectual property license and supply agreement with Cordis, there are certain restrictions on our ability to sell the ENROUTE stent through select direct competitors of Cordis. If we are unable to locate international distributors that are not select direct competitors to Cordis, to market and sell our ENROUTE stent, our ability to expand our business internationally may be harmed, which could have a material adverse effect on our business, financial condition and results of operations.

In anticipation of our international expansion into Japan and China, we recently entered into exclusive distribution agreements with distributors to sell our products in these countries. Exclusive distribution arrangements, however, involve risk and these distributors and any future distributor we engage may not effectively distribute our products. Our future sales in Japan and China, once we obtain reimbursement and launch our products in those countries, will depend in large part on the distributors with whom we have entered into exclusive distribution agreements in those countries. While we believe we have selected experienced and qualified distributors in these countries, we will be completely dependent on their efforts to market and sell our products in these countries, and we will be unable to control their efforts completely. In addition, we are unable to ensure that our distributors will comply with all applicable laws regarding the marketing and sale of our products. If our distributors fail to effectively market and sell our products, or comply with all applicable laws, our operating results and business may suffer. We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business. The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We recently completed the process of further enhancing policies and procedures with the intent to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks

arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations. We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants, independent contractors, and commercial partners. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with governmental laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCPA or a similar state law, or the impact of such actions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

Risks Related to Our Intellectual Property

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products. The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U. S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and / or export our products or to use product names. Moreover, in recent years, individuals and groups that are non- practicing entities have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or " invitations to license, " or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management' s attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third- party' s patent or trademark or of misappropriating a third- party' s trade secret. Since some patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know- how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. Further, if patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third- party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement. Similarly, interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations. Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents, trademarks or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents are found to be valid and infringed, a court may refuse

to grant injunctive relief against the infringer and instead grant us monetary damages and / or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations. Our success depends on our ability to obtain, maintain and protect our intellectual property rights. In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated. We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. We cannot assure that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U. S. and foreign- issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and / or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. " Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties or could prevent us from manufacturing, selling or using the product, any of which could severely harm our business. If we are unable to protect the confidentiality of our other proprietary information, our

business and competitive position may be harmed. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries may not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in research and development or acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations. Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business. We may not be able to protect our intellectual property rights throughout the world. A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have sufficient patent protection and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them

from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own. Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a “first-to-invent” system to a “first-to-file” system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations. Further, the Leahy-Smith Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts, and use a lower burden of proof than used in litigation in U.

S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U. S. patent invalidated in a USPTO post- grant review or inter partes review proceeding than invalidated in a litigation in a U. S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we, our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands and managing through regulatory implications such as relabeling. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In other cases, our competitors may associate our marks, such as TCAR, with their products and infringe upon our intellectual property as a result. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

Risks Related to Government Regulation Healthcare policy changes, including recently enacted legislation reforming the U. S. healthcare system, could harm our business, financial condition and results of operations. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act: • Established a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; • Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and • Expanded the eligibility criteria for Medicaid programs. The taxes imposed by the Affordable Care Act and the expansion in the government’ s role in the U. S. healthcare industry may result in decreased sale of our products and, lower reimbursement by payers for our products, all of which may have a material adverse effect on our business, financial condition and results of operations. Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. It is unclear how the other healthcare reform measures of the Biden administration or future litigation will impact the ACA or our business. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2 % per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031-2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of March 31, 2022, unless additional Congressional action is taken. Under current legislation, starting on April 1, 2022, the actual reduction in Medicare payments can vary from 1 % in 2022 to up to 4 % in the final fiscal year of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians’ participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows. We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. They could result in reduced demand for our products or result in additional pricing pressure. Any such reforms could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition and results of operations. Changes and reforms in the European Union, Japan and China and other countries

where we may decide to commercialize could have similar effects. **Effective October 11, 2023, CMS published the final decision memo for NCD 20.7 expanding coverage for CAS, including TCAR, under indication B4 for both high risk and standard surgical risk patients. The revised NCD 20.7 does not impact existing TCAR coverage under indication B3 for FDA- approved post- approval studies such as the VQI TSP. CMS determined that coverage of percutaneous transluminal angioplasty, or PTA, of the carotid artery concurrent with stenting, including TCAR, under indication B4 is reasonable and necessary with the placement of an FDA- approved carotid stent and with an FDA- approved or cleared embolic protection device, in patients with symptomatic carotid artery stenosis $\geq 50\%$ and in patients with asymptomatic carotid artery stenosis $\geq 70\%$ under the following conditions: (1) Neurological assessment must be performed by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS. (2) First-line evaluation of carotid artery stenosis must use duplex ultrasound. (3) Computed- tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, must be used to confirm degree of stenosis, and provide information about the aortic arch, and extra and intra- cranial circulation. (4) Intra- arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non- invasive imaging results or contraindicated for CTA or MRA. Prior to furnishing CAS, the practitioner must engage in a shared decision- making interaction with the beneficiary, which must include: (1) Discussion of all treatment options for carotid stenosis, including CEA, CAS (which includes TCAR), and optimal medical therapy (OMT). (2) Explanation of risks and benefits for each option specific to the beneficiary' s clinical condition. (3) Integration of clinical guidelines (e. g., patient co- morbidities and concomitant treatments). (4) Discussion and incorporation of beneficiary' s personal preferences and priorities in choosing a treatment plan. Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. However, CMS facility approval or certification is not required. The Medicare Administrative Contractors will have discretion to make carotid artery stenting coverage determinations not addressed in NCD 20.7. As a result of the expansion of coverage in NCD 20.7 and CMS' s stated goals for broader patient access, we believe there could be rising interest and awareness in minimally invasive carotid stenting procedures including TCAR.**

Our products have in the past and could in the future be subject to product recalls that could harm our reputation or increase the probability of inspection by, or additional scrutiny from, the FDA or other relevant regulatory bodies. The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us has occurred, and could occur again in the future, as a result of component failures, manufacturing errors or design or labeling defects. In January 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System. Additional recalls of our products would divert managerial attention, be expensive, harm our reputation with customers, result in additional scrutiny from the FDA or other relevant regulatory bodies and harm our financial condition and results of operations. Additional recall announcements could also negatively affect our stock price. Changes in the CMS fee schedules may affect our hospital customers and thereby harm our revenue and operating results. Government payers, such as Centers for Medicare and Medicaid Services, or CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U. S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third- party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third- party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations. If we fail to comply with broad- based healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected. The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation: • Federal and state laws and regulations regarding billing and claims payment applicable to TCAR and regulatory agencies enforcing those laws and regulations; • FDA prohibitions against the advertisement, promotion and labeling of our products for off- label uses, or uses outside the specific indications approved by the FDA; • The federal Anti- Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the CMS programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti- Kickback Statute may result in civil monetary penalties per violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment. Similarly, violations can result in mandatory

exclusion from participation in government healthcare programs, including Medicare and Medicaid; • The federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs; • Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters; • The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • The FCPA, the U. K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities; • The federal Physician Payment Sunshine Act, or Open Payments, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, and its implementing regulations, which requires applicable manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the U. S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Our failure to submit required information on time may result in civil monetary penalties with additional amounts for “knowing failures”, for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations; and • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Failure to comply with the HIPAA privacy and security standards when applicable can result in civil monetary penalties, and, in certain circumstances, criminal penalties including fines and / or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state. Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E. U. General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers. **Analogous foreign law equivalents are more fully described in the section titled “Business — Government Regulation.”** Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. We may be subject to private “qui tam” actions brought by individual whistleblowers on behalf of the federal or state governments. The growth of our business and sales organization and our planned expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results. Changes in tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions. We are subject to tax laws, regulations, and policies of the several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions and / or our tax liabilities. For example, in August 2022 the United States enacted a 1 % excise tax on stock buybacks and a 15 % alternative

minimum tax on adjusted financial statement income for certain large corporations as part of the Inflation Reduction Act of 2022. Further, many countries, and organizations such as the Organization for Economic Cooperation and Development have proposed implementing changes to existing tax laws, including a proposed 15 % global minimum tax. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. There can be no assurance that our effective tax rates, tax payments, or tax credits and incentives will not be adversely affected by these or other developments or changes in law. If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed. Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide ranging and govern, among other things: • Product design, development and manufacture; • Laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution; • Premarketing clearance or approval; • Record keeping; • Product marketing, promotion and advertising, sales and distribution; and • Post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals. Before a new medical device, ~~including our recently FDA approved Investigational Device Exemption, or IDE, for our feasibility study in acute ischemic stroke, NITE-1,~~ or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510 (k) clearance pursuant to Section 510 (k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies. In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510 (k) clearance process. In the 510 (k) clearance process, the FDA must determine that a proposed device is “ substantially equivalent ” to a device legally on the market, known as a “ predicate ” device, in order to clear the proposed device for marketing. To be “ substantially equivalent, ” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510 (k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510 (k) may require a new 510 (k), or such modification may put the device into class III and require PMA approval. The FDA’s 510 (k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations. Over the last several years, the FDA has proposed reforms to its 510 (k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510 (k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510 (k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510 (k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510 (k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In September 2019, the FDA issued revised final guidance describing an optional “ safety and performance based ” premarket review pathway for manufacturers of “ certain, well-understood device types ” to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the “ safety and performance based ” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510 (k) clearances or otherwise create competition that may negatively affect our business. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. **For example, the FDA issued a final rule in February 2024 replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485: 2016. The FDA has stated that the standards contained in ISO 13485: 216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026.** Any new statutes, regulations, or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market, or distribute our products. The FDA’s and other regulatory authorities’ policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay regulatory clearance or approval of our product candidates. **If the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA’s authority, lead to uncertainties in the industry, and disrupt FDA’s normal operations, which could delay FDA’s review of our marketing applications.** We cannot determine what effect changes in regulations, statutes, legal interpretation, or policies, when and if promulgated, enacted, or adopted may

have on our business in the future. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- Our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- An advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- The applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third-party contract manufacturers;
- The potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- The FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance. Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA, **PMDA**, and **NMPA** **European Union** regulatory authorities strictly regulate the labeling, promotion and advertising of our products, including comparative and superiority claims vis a vis competitors' products, that may be made about products. As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. For example, as a condition of the FDA approval for the label expansion for ENROUTE stent to include patients at standard risk for adverse events from carotid endarterectomy, in September 2022, we announced the enrollment of the first patient in ROADSTER 3, our prospective, multi-center, single-arm study to assess real-world treatment of standard surgical risk patients with carotid artery disease using TCAR. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business. As discussed above, findings of meaningfully higher rates of adverse events or any unexpected safety or efficacy concerns related to our approval products in such post-approval study or any other independent studies or reports can result in FDA withdrawal or restriction of our PMA approval, which can have a material adverse effect on our business prospects, reputation, and market acceptance of our products. In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites and facilities as part of its review process. **We have a robust post-market surveillance and complaint handling system which provides for timely communication between our field employees and customers and our internal Quality Assurance team. Information regarding our products and user and patient experiences is reviewed and, where appropriate, regulatory authorities are notified.** **adverse Adverse** events and device malfunctions **including, but not are reported in the United States to the FDA and publicly limited listed in the Manufacturer to, stroke, arterial dissection, tip detachment, stent thrombosis and wound complications User Facility Device Experience (MAUDE) database.** If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to an additional inspection by, or increased scrutiny from, the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by Cordis. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted. The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is

neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity, warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. The FDA and state authorities have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions: • Adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties; • Repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products; • Operating restrictions, partial suspension or total shutdown of production; • Denial of our requests for 510 (k) clearance or premarket approval of new products, new intended uses or modifications to existing products; • Withdrawal of 510 (k) clearance or premarket approvals that have already been granted; and • Criminal prosecution. If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

We are subject to United States and certain foreign laws and regulations relating to export and import controls, sanctions, embargoes, anti- corruption, and anti- money laundering. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which would harm our business. We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended (FCPA), the United States domestic bribery statute contained in 18 U. S. C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. International trade, tariff, and import / export laws and regulations may require us to obtain licenses or permits in order to complete certain activities necessary for the research, manufacture, and development of our product candidates. Moreover, we expect such laws and regulations, along with associated guidance and interpretations, to evolve over time in ways that may impact various aspects of our business. The process for obtaining any necessary licenses or permits may be lengthy and time- consuming, and if we are not able to obtain any such licenses or permits in a timely manner, we may experience delays in our ability to manufacture, develop, and commercialize our product candidates. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, collaborators, and other third parties from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell products, if any, for which we receive regulatory approval outside the United States, to conduct clinical trials, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. In the ordinary course of our business, we may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We may be held liable for the corrupt or other illegal activities of our employees, agents, contractors, collaborators, and other third parties, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross- border operations. The U. S. government has made and continues to make significant additional changes in U. S. trade policy and may continue to take future actions that could negatively impact U. S. trade. For example, legislation has been introduced in Congress to limit certain U. S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U. S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and / or results of operations would be materially and adversely affected.

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

halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following: • The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold; • Patients do not enroll in clinical trials at the rate expected; • Patients do not comply with trial protocols; • Patient follow-up is not at the rate expected; • Patients experience adverse events; • Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial; • Device malfunctions occur with unexpected frequency or potential adverse consequences; • Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing; • Institutional review boards and third-party clinical investigators may delay or reject the trial protocol; • Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements; • Third-party investigators are disqualified by the FDA; • We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations; • Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests; • Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials; • Changes in government regulations or administrative actions; • The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or • The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness. Material modifications to our products may require new 510 (k) clearances, premarket approval, or ~~CE Marks~~ **other international regulatory submissions**, or may require us to recall or cease marketing our products until new clearances or approvals are obtained. Material modifications to the intended use or technological characteristics of our products ~~will~~ **may** require new 510 (k) clearances, premarket approvals, or ~~CE Marks~~ **other international regulatory submissions** prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products **may** require prior FDA approval of a PMA supplement **or may require international regulatory activity**. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared **or approved** device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510 (k) clearance or approval of a PMA supplement. **Similar requirements for approval of significant changes are in place in international markets.** We may not be able to obtain additional 510 (k) clearances ~~or~~, premarket **approvals, or international** approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA, **PMDA**, or **NMPA** ~~an EU Notified Body~~ **disagrees** ~~disagree~~ and **requires** ~~require~~ new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions. In July 2022, we voluntarily requested the cancellation of our CE Mark certifications for business reasons but will continue to work with our ~~Certified~~ **Certification** Body to maintain ISO 13485: 2016 certification **of our quality system**. The CE Certificates were cancelled, effective August 23, 2022, but the ISO 13485: 2016 certification remains in effect. We may seek new CE Mark certifications in the future. If we, or our suppliers, fail to comply with the FDA's QSR, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer. Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the QSR, which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations. **The FDA issued a final rule in February 2024 replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485: 2016. The FDA has stated that the standards contained in ISO 13485: 216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026.** In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA and state authorities. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline. We are registered with the FDA as a medical device specifications developer, manufacturer and complaint file establishment. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health, or CDPH, to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof. **The FDA conducted an initial facility inspection in our Plymouth, Minnesota location in January 2024 and a one-observation**

Form 483 Notice of Observation was issued pertaining to a singular piece of production equipment in relation to calibration and preventive maintenance. In response, we initiated a Corrective and Preventive Action, or CAPA, to address the 483. We can provide no assurance that we will continue to remain in material compliance with the QSR. If the FDA or CDPH inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business. **Inadequate funding for the FDA, the SEC, the CMS and other government agencies as a result of a U. S. federal government shutdown could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in the past as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.** Environmental, social and corporate governance (, or ESG) matters, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation. There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders on ESG matters including climate change, energy and water use, plastic waste and other sustainability concerns. Additionally, public interest and legislative pressure related to public companies' ESG practices, including rules related to climate change and climate- related disclosures, continue to grow. For example, in 2022, the SEC published a proposed rule that would require companies to provide significantly expanded climate- related disclosures at, **and in October 2023, the State of California adopted broad climate reporting laws that will require certain businesses to report on greenhouse gas (GHG) emissions and climate- related financial risk. Compliance with these climate- related disclosures may result in** significant costs and operational impacts **to comply** and impose increased oversight obligations on our board of directors and management. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, diversity in our employee base or on our board of directors, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single- use and non- recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs. If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our company, and customers and consumers may choose to stop purchasing our products, which could have a material adverse effect on our reputation, business or financial condition. Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability. Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third- party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results. **New climate- related reporting rules in California and other jurisdictions could require significant time, attention, and resources from management, and could also lead to increased costs and liabilities. In March 2022, the SEC proposed new rules that would require public companies to disclose extensive climate- related information in their registration statements and periodic reports. The proposed rules would mandate disclosures related to climate- related risks and their impacts, GHG emissions, and climate- related financial statement metrics. In October 2023, the State of California**

adopted the Climate Corporate Data Accountability Act and the Climate- Related Financial Risk Act. These broad climate reporting laws that would require certain businesses doing business in California to report on GHG emissions and climate- related financial risks. As a company that files periodic reports with the SEC and that has operations in California, we may fall under the jurisdiction of these new laws, which impose rigorous reporting obligations regarding our GHG climate- related financial risks and extensive requirements for the disclosure of GHG emissions. Compliance with these climate- related disclosure rules will require substantial time and attention of management and financial resources. We must develop robust systems, processes, and controls for assessing and reporting our climate- related financial risks, as well as ensuring transparency and accuracy in our disclosures.

Risks Related to Ownership of Our Common Stock

The market price of our common stock in the past has been and may continue to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. The market price of our common stock can in the past have been and may continue to be highly volatile and may fluctuate substantially due to many factors, including, without limitation:

- Analysts' estimates, estimates and investors' perceptions, recommendations regarding our business, prospects and the value of our common stock by securities analysts, the loss of analyst coverage or our failure to achieve analysts' estimates, which failure to achieve analysts' consensus estimates occurred with both our first quarter 2023 and third quarter 2023 financial results;
- Perceptions by securities analysts and other investors regarding our business, prospects and the value of our common stock, including without limitation, the total market opportunity for our products, our ability to penetrate the market, the effect of the revised NCD 20. 7 and the effect on our business and results of operations, including without limitation pricing, of competitive stents and products;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue and other factors, such as pricing and the effect of stocking orders if we sell to international distributors;
- The financial and business projections we may provide to the public, any changes in these projections or our failure to meet these projections, which occurred when we revised downward our annual revenue guidance in October 2023;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation, interest rate and economic policies, supply chain issues, the impact of GLP- 1 usage, geopolitical tensions including the war between Russia and Ukraine, the war between Israel and Hamas and changes in China- Taiwan relations;
- Changes in reimbursement by current or potential payers, including CMS' s final decision on to reconsider NCD 20. 7, Percutaneous Transluminal Angioplasty, that provides coverage for CAS including, to be updated to provide coverage for the full range of patients that could benefit from the TCAR procedure;
- Operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials as well as studies and registries conducted by others using our products;
- The results of clinical trials that study competing carotid interventions or medical management of carotid artery disease;
- The loss of key personnel, including changes in our board of directors and management, such as the recent retirement of our prior CEO and appointment of a new CEO;
- Product recalls, backorders or other problems associated with our products;
- Our ability to obtain required approvals and reimbursement coverage for our products internationally and successfully launch and sell our products in such markets;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry; and
- Other risks and uncertainties described in this report.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility, especially significant drops. If we were to become involved in securities stock price like we have recently experienced. Such litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock. We are obligated to maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting and any failure to maintain the adequacy of our internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10- K each year. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are also required to comply with, among other requirements, the auditor attestation requirements of Section 404 in our Annual Report on Form 10- K each year. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We have engaged outside consultants who function in the capacity of an internal audit group, and we will plan to continue to hire additional consultants, accounting and financial staff with appropriate public company experience and technical accounting knowledge as we maintain the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in

the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy our current and any future material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Anti- takeover provisions in our ~~amended and restated~~ **amended and restated** certificate of incorporation and ~~amended and restated~~ **amended and restated** bylaws, and Delaware law, could discourage a change in control of our company or a change in our management. Our ~~amended and restated~~ **amended and restated** certificate of incorporation and ~~amended and restated~~ **amended and restated** bylaws contain provisions that might enable our management to resist a takeover. These provisions include, **among others**: • Advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice; • A supermajority stockholder vote requirement for amending certain provisions of our ~~amended and restated~~ **amended and restated** certificate of incorporation and ~~amended and restated~~ **amended and restated** bylaws; • The right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer; ~~• 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. ~~65~~ **These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any 74**