Penumbra Inc
Form 10-K
February 26, 2019

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

FORM 10-K

(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 001-37557

Penumbra, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	05-0605598
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Penumbra Place Alameda, CA	94502
(Address of Principal Executive Offices)	(Zip Code)

(510) 748-3200
(Registrant's telephone number, including area code)

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

Title of each class	Name of Each Exchange on Which Registered
Common Stock, Par value $0.001 per share	The New York Stock Exchange

Securities registered pursuant of Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: x No: o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: o No: x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: x No: o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes: x No: o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

As of June 30, 2018, the aggregate market value of the registrant’s common stock held by nonaffiliates was approximately $4.3 billion, based on the closing price as reported on the New York Stock Exchange as of such date.

As of February 12, 2019, the registrant had 34,653,172 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement for its 2019 annual meeting of stockholders, which is to be filed not more than 120 days after the registrant’s fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements in addition to historical information. These forward-looking statements are included throughout this Form 10-K, including in the sections entitled “Business,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in other sections of this Form 10-K. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “opportunity” or “ negative of these terms and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section titled “Risk Factors.” You should specifically consider the numerous risks outlined in the section titled “Risk Factors.” Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. We undertake no obligation to update any forward-looking statements made in this Form 10-K to reflect events or circumstances after the date of this Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law.

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PART I

ITEM 1. BUSINESS.

Overview

References herein to “we,” “us,” “our,” “Company,” and “Penumbra,” refer to Penumbra, Inc. and its consolidated subsidiaries unless the context specifically states otherwise.

Penumbra is a global healthcare company focused on innovative therapies. We design, develop, manufacture and market medical devices and have a broad portfolio of products that addresses challenging medical conditions and significant clinical needs across our major markets. Our team focuses on developing, manufacturing and marketing products for use by specialist physicians to drive improved clinical outcomes. We believe that the cost-effectiveness of our products is attractive to our hospital customers.

Since our founding in 2004, we have had a strong track record of organic product development and commercial expansion that has established the foundation of our global organization. We have successfully developed, obtained regulatory clearance or approval for, and introduced products into the neurovascular market since 2007, vascular market since 2013 and neurosurgical market since 2014, respectively. We continue to expand our portfolio of product offerings, while developing and iterating on our currently available products.

We attribute our success to our culture built on cooperation, our highly efficient product innovation process, our disciplined approach to product and commercial development, our deep understanding of our target end markets and our relationships with specialist physicians. We believe these factors have enabled us to rapidly innovate in a highly efficient manner.

We sell our products to hospitals primarily through our direct sales organization in the United States, most of Europe, Canada and Australia, as well as through distributors in select international markets. We generated revenue of $444.9 million, $333.8 million and $263.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. This represents an annual increase of 33.3% and 26.8%, respectively. We generated operating losses of $0.9 million and $1.4 million for the years ended December 31, 2018, and 2016, respectively, and operating income of $1.2 million for the year ended December 31, 2017.

Our Markets

We concentrate on improving treatment outcomes for patients with certain forms of vascular disease. Vascular disease refers to any condition that affects the circulatory system and typically manifests as a blockage or rupture of an artery or a vein. When the treatment for vascular disease is performed from within a vessel, it is referred to as an endovascular procedure. Endovascular device markets are conventionally classified according to the anatomic location of the disorder, and are generally divided into neuro, which includes neurovascular and neurosurgical, and vascular, which includes peripheral vascular and cardiovascular. In both of these markets, our main product technologies include thrombectomy devices to remove clots and embolization devices to treat aneurysms and to occlude vessels. We generated revenue of $294.3 million, $232.4 million and $185.5 million from our neuro product category for the years ended December 31, 2018, 2017 and 2016, respectively. We generated revenue of $150.6 million, $101.3 million, and $77.8 million from our vascular product category for the years ended December 31, 2018, 2017 and 2016, respectively. While we operate in these two broad markets, the Company has one business activity: the design, development, manufacturing and marketing of innovative medical devices, and operates as one operating segment. While reliable third party data is not available for many markets outside the United States, we believe that there is a substantial additional market for our neuro and vascular products throughout the world.

The Neuro Market

The neuro market is comprised of vascular diseases and disorders in the brain, including ischemic stroke, hemorrhagic stroke, brain aneurysms and other conditions. Globally, stroke is the second-leading cause of death and the third-leading cause of serious long-term disability. In the United States, the American Heart Association (“AHA”) and American Stroke Association (“ASA”) estimated that approximately 795,000 strokes occur annually, and lead to approximately 140,000 deaths per year. The AHA and ASA estimated that in 2018 stroke was the fifth-leading cause of death in the United States. The AHA reports that someone in the United States has a stroke every 40 seconds, and every four minutes, someone dies from stroke.

The principal neuro markets that we operate in are:

- Ischemic Stroke: Ischemic strokes, caused by the blockage of an artery in the brain, represent approximately 87% of strokes, or approximately 700,000 patients annually, in the United States. Of these cases, we estimate that approximately 200,000 are treatable with mechanical thrombectomy, which involves removal of the clot causing the blockage by mechanical means and restoring blood flow to the blocked vessels. Studies have shown that

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patients treated with mechanical thrombectomy had improved functional outcomes compared with treatment with clot-busting drugs such as tPA alone.

- Brain Aneurysm: An aneurysm is a weak area in a blood vessel that usually enlarges and is often described as a "ballooning" of the blood vessel. Approximately 1.5% to 5.0% of the general population has or will develop a brain aneurysm and about 6 million people in the United States may currently have a brain aneurysm. If a patient has had an aneurysm, there is a 15% to 20% likelihood that the patient will have one or more additional aneurysms. The primary endovascular procedure for treating unruptured aneurysms uses a repair technique called embolization, in which the aneurysm is packed with coils in a minimally invasive procedure.
- Hemorrhagic Stroke: Hemorrhagic strokes, caused by the sudden rupture of a brain artery that leads to bleeding into or around the brain, represent approximately 13% of strokes, or approximately 100,000 patients annually, in the United States. Brain aneurysms and arteriovenous malformations ("AVM") can both cause hemorrhagic stroke. According to independent sources, every year 0.5% to 3.0% of people with a brain aneurysm and 1.0% to 3.0% of people with an AVM may suffer from bleeding. According to the AHA and ASA, once a brain aneurysm or an AVM bleeds, the chance of death is 30% to 40% and 10% to 15%, respectively. Intracerebral hemorrhage ("ICH"), a type of hemorrhagic stroke, occurs when a vessel within the brain bursts, allowing blood to leak inside the brain.

In addition to products specifically addressing these disease states, we operate in the market for neuro access products, which facilitate the delivery of interventional treatments in the brain.

The Vascular Market

Vascular diseases are diseases occurring in vessels outside of the brain. Such diseases are very similar to those experienced in the neurovasculature. Just as the disruption of blood flow to the brain has high mortality and morbidity, disruptions in the peripheral vasculature can also have serious adverse consequences.

The principal vascular markets that we operate in are:

- Peripheral Thrombectomy: There are more than one million incidences of clot in the peripheral vasculature each year in the United States and we estimate that approximately 150,000 are interventionally treated.

Venous Thromboembolism ("VTE"): Deep Vein Thrombosis, ("DVT") and Pulmonary Embolism ("PE") are collectively referred to as VTE. DVT occurs when a blood clot develops in veins deep in the body and PE occurs when a blood clot becomes lodged in the lung. DVT can result in PE if a blood clot in the leg breaks loose and travels to the lungs. According to the Centers for Disease Control and Prevention ("CDC"), up to 900,000 people are affected by VTE each year in the United States, of which we estimate up to 600,000 are incidences of DVT. It is estimated that one-third of people with VTE will have a recurrence within 10 years, and it is estimated that there are more than 100,000 VTE-related deaths in the United States annually. Sudden death is the first symptom in approximately 25% of the patients who have a PE.

Peripheral Arterial Occlusion ("PAO"): PAO occurs when a blood clot develops in major peripheral arteries. We estimate that there are approximately 175,000 incidences of PAO each year in the United States.

- Peripheral Embolization: Coil embolization is used to treat numerous conditions in the peripheral vasculature including aneurysms, hemorrhage, endoleaks and varicoceles. Based on independent market research, there are approximately 45,000 peripheral vascular embolization coil procedures in the United States each year. We estimate that one-third of coils used in the United States are detachable coils, with the remainder being pushable coils.

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Our Product Portfolio

Since our founding in 2004 we have developed a product portfolio that includes 6 product families within our major markets. The following table summarizes our product offerings.

Product Families		Key Product Brands	Descriptions
NEURO	Access	Neuron Neuron MAX Select BENCHMARK DDC PX SLIM	Neurovascular access systems designed to provide intracranial access for use in a wide range of neurovascular therapies
	Thrombectomy	Penumbra System, including Penumbra JET, ACE and the 3D Revascularization Device, Penumbra ENGINE and other components and accessories	Aspiration based thrombectomy systems and accessory devices, including revascularization device designed for mechanical thrombectomy
	Embolization	Penumbra Coil 400	Neurovascular embolization coiling system designed to treat patients with large aneurysms and other large neurovascular lesions
		Penumbra SMART COIL	Neurovascular embolization coiling system designed to treat patients with all sizes of aneurysms and other neurovascular lesions
	Neurosurgical Tools	Artemis Neuro Evacuation Device	Neurosurgical aspiration tools for the removal of tissue and fluids
VASCULAR	Thrombectomy	Indigo System	Aspiration-based thrombectomy system for vascular applications, currently for use in the peripheral and coronary vasculature
	Embolization	Ruby Coil	Large-volume, detachable embolic coil system for peripheral embolization
		LANTERN	Microcatheter for delivery of detachable coils and occlusion devices
		POD (Penumbra Occlusion Device)	Detachable, microcatheter-deliverable occlusion device designed specifically to occlude peripheral vessels
		Packing Coil	Complementary device for use with Ruby Coil and POD for vessel occlusion

Neuro Products

Our neuro products fall into the following broad product families:

Thrombectomy Products

Our Penumbra System brand of products offers a form of mechanical thrombectomy used by specialist physicians to revascularize blood vessels that are blocked by clots in the intracranial vasculature. These products are aspiration-based. The Penumbra System is a fully integrated mechanical thrombectomy system consisting of reperfusion catheters and separators, the 3D Revascularization Device, aspiration tubing, and aspiration pump. Penumbra System Reperfusion Catheters are the cornerstone of the Penumbra System and are manufactured using a variety of proprietary processes and materials science innovations. Our reperfusion catheters are cleared by the FDA

for use in revascularization of patients with acute ischemic stroke.

The Penumbra System Reperfusion Catheters, powered by Penumbra ENGINE or Penumbra Pump MAX, are designed for trackability and to maximize thrombus removal force. We believe these design features contribute to improved clinical outcomes and reduced procedure times. Penumbra System Reperfusion Catheters include the latest Penumbra JET family, ACE family and MAX families of catheters, designed to address a broad range of occlusions. The Penumbra JET 7 has the largest lumen of the catheter families and offers the greatest aspiration power with the Penumbra ENGINE. The Penumbra JET D is designed to maximize aspiration power for distal occlusions.
3D is a revascularization component of the Penumbra System that offers a technology-advanced structure designed to treat large vessel occlusion in combination with Penumbra Jet7 and ACE Reperfusion Catheters. The 3D Revascularization

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Device is cleared by the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and CE mark submission is currently under review.

Penumbra Separators enable a physician to remove an aspirated clot that has aggregated in the reperfusion catheter during the procedure. The Separators were an important component of our earlier Penumbra System due to the smaller diameter of our original reperfusion catheters. With the launch of our larger diameter ACE catheters, Separators are less frequently used by physicians today than they were with earlier generation reperfusion catheters.

Penumbra ENGINE or Penumbra Pump MAX is connected to our reperfusion catheters and provides the aspiration suction force. We developed our proprietary aspiration source as a fully-integrated system specifically for mechanical thrombectomy by aspiration.

Embolization Products

Penumbra SMART COIL is a family of detachable coils, designed to treat patients with a wide range of neurovascular lesions, including the small and medium sized aneurysms that comprise the majority of the neurovascular coiling market. The design of Penumbra SMART COIL allows the level of softness to be determined not only by the diameter of the platinum filament, but also by a structural component inside the coil itself. This development enables Penumbra SMART COIL to become progressively softer within the span of an individual coil.

Penumbra Coil 400 is a family of detachable coils developed to offer an improved alternative for the treatment of larger aneurysms and other larger, more complex lesions. We implemented several proprietary design innovations to enable the coil to maintain shape while achieving biomechanically stable occlusion. Given the size and handling of Penumbra Coil 400, it is able to achieve higher packing density with fewer coils compared to competitive coiling systems.

Access Products

Most endovascular procedures require access to the diseased area using guidewires and catheters. Accessing the brain through the tortuous neurovasculature has been a substantial challenge for physicians treating vascular disorders in the brain. Companies that developed catheters and other products for neurovascular applications historically leveraged technologies developed for use in coronary or peripheral vascular interventions. This approach created challenges given the vastly different anatomy, structure and sizing of the neurovascular vessels.

The Neuron family of guide catheters and the Penumbra distal delivery catheters ("DDC") enable many endovascular procedures in the tortuous anatomy of the neurovasculature. The Neuron delivery catheter is a variable stiffness guide catheter with increased support in the aortic arch, easier access, and trackability into the intracranial vasculature. The design of Neuron enables physicians to position the catheter much higher in the anatomy than conventional guide catheters.

The BENCHMARK catheter features additional improvements in aortic arch support, ease-of-use, and trackability. In addition to improved proximal support in the arch through multi-geometry metal reinforcement, the distal tip is softer and more trackable, while maintaining distal shaft radiopacity for improved visualization. The BENCHMARK also is available pre-packaged with a Select catheter to obviate the need for a neurovascular guide catheter exchange, which may reduce the number of devices needed per procedure and shorten procedure times.

Neurosurgical Tools

Artemis Neuro Evacuation Device leverages our expertise in thrombectomy and access to offer a minimally invasive approach to surgical removal of fluid and tissue from the ventricles and cerebrum. The Artemis Neuro Evacuation Device works with a neuroendoscope through a sheath to access hematomas. Together with the Penumbra Pump MAX aspiration source, Artemis offers powerful and controlled hematoma evacuation.

Vascular Products

The peripheral vasculature presents unique challenges that differ from the neurovasculature. Many peripheral arteries and veins are significantly larger than those found in the brain and therefore have higher blood flow rates. More importantly, they must be able to accommodate larger pressure gradients and sustain structural integrity despite substantial movement and flexing of the organs and musculature that surround them. Imaging can also be more challenging as physicians have to view their equipment through many more layers of organs and tissue than in the brain. The coronary vasculature also presents unique challenges.

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Our vascular products fall into the following broad product families:

Embolization

Ruby Coil System

The Ruby Coil System consists of detachable coils that are specifically designed for peripheral applications. Ruby Coils have a controlled mechanical detachment mechanism that permits the physician to deliver and reposition the coil until the final satisfactory position is reached before detachment.

The Ruby Coil System is used in a variety of clinical applications, including, but not limited to:

- active extravasations, or the escape of blood into surrounding tissue;
- selective embolization in patients with visceral aneurysms;
- exclusion of branches prior to chemoembolization and radioembolization;
- embolization in patients with gastrointestinal bleeding;
- embolization of branches prior to stent graft procedures;
- procedures after stent grafting in patients with persistent type II endoleaks and sac enlargement;
- treatment of patients with varicocele and pelvic congestion syndrome;
- high flow arterial venous malformations;
- post trans intrahepatic shunt placement;
- balloon retrograde transvenous obliteration; and
- exclusion of hepatic branches prior to liver resection.

LANTERN

The Penumbra LANTERN Delivery Microcatheter is a low-profile microcatheter with a high-flow lumen that enables large-volume coil delivery. LANTERN features a radiopaque distal shaft for enhanced visibility and dual distal marker bands for precise coil deployment in tortuous anatomy.

POD (Penumbra Occlusion Device) System

POD addresses a specific need in the peripheral embolization market to rapidly and precisely occlude a target vessel. Our POD device utilizes technology that delivers both variable sizing and variable softness to provide a single device solution for rapid and precise embolization of the target vessel. The technology achieves this range of features through the design of a distal anchoring segment, thereby immediately anchoring the device in a range of vessel diameters. The proximal segment of the POD achieves dense occlusion by packing a softer, smaller diameter segment tightly behind the anchored portion.

The Packing Coil is a complementary device for use with our other peripheral embolization products. It is uniquely designed to pack densely behind Ruby Coils and POD to occlude arteries and veins throughout the peripheral vasculature including aneurysms. Both POD and Packing Coil are detached instantly with a sterile detachment handle.

Thrombectomy

Indigo System

The Indigo System was designed for continuous aspiration mechanical thrombectomy (“CAT”), leveraging the success of the Penumbra System in ischemic stroke. It is an easy to use thrombectomy system that is powerful, highly trackable, and suited to a wide range of clot morphology in both the peripheral arterial, peripheral venous and coronary vasculature. The Indigo System is comprised of three principal components:

- Continuous Aspiration Mechanical Thrombectomy Catheters are robust, durable, trackable and suited for the peripheral and coronary anatomy. We have introduced multiple sizes of catheters for use in both the peripheral and coronary vasculature.
- Indigo Separators are advanced and retracted through the CAT catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the catheter tip. In the peripheral vasculature, clots often form in long segments and are more resistant to traditional aspiration techniques. The Indigo System with the Separator enables a practitioner to remove a wide range of clot morphology from both peripheral and coronary vasculature.

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- Penumbra ENGINE or Penumbra Pump MAX is connected to our CAT catheters and provides the aspiration suction force. We developed our proprietary aspiration source as a fully-integrated system specifically for mechanical thrombectomy by aspiration.

Research and Development

Our research and development team has a track record of product innovation and significant product improvements. Since inception, we have introduced multiple brands in either the United States, international markets, or both. We believe our ability to rapidly develop innovative products is in large part attributable to the fully integrated product innovation process that we have implemented, and the management philosophy behind that process. In addition, we have recruited and retained engineers with a variety of backgrounds and experience to support the development of innovative therapies. Substantially all of our research and development efforts are based at our campus in Alameda, California.

Manufacturing

We currently maintain our manufacturing facilities at our campus in Alameda, California and currently produce substantially all of our products in-house. Our manufacturing facilities are International Organization for Standardization ("ISO") 13485 compliant with ISO 13485:2016 certification achieved in 2018. In 2007, we achieved compliance with the European Union's Medical Device Directive ("MDD"), allowing our products to be CE marked. We received our most recent re-certification to the MDD in June 2018. We have elected to participate in the Medical Device Single Audit Program ("MDSAP") which allows for certification and review of compliance to standards and regulations required in the United States, Canada, Brazil, Australia, and Japan by a single auditing organization. We received our first MDSAP certification in August 2018.

We use annual internal audits to ensure strong quality control practices. An internal, on-going staff training and education program contributes to our quality assurance program; training is documented and considered part of the employee evaluation process.

We believe we have adequate supplies or sources of availability of raw materials necessary to meet our needs. However, there are risks and uncertainties with respect to the supply of raw materials, particularly where provided by a single supplier, which could impact availability in sufficient quantities to meet our needs. In an effort to manage risk associated with raw materials supply, we work closely with suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. We also utilize long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Where possible, we seek second source suppliers or suppliers that have alternate manufacturing sites at which they could manufacture our parts.

Sales and Marketing

We sell our products directly in the United States, most of Europe, Canada and Australia. We have complemented our direct sales organization with distributors in Japan and most other international markets. We have regulatory clearance/approval to sell certain of our neuro access, thrombectomy and embolization products, neurosurgical tools, and vascular embolization and thrombectomy products in two of our three major markets, the United States and Europe. In our third major market, Japan, we have regulatory approval to sell our neuro thrombectomy and embolization products and vascular embolization products.

We currently sell our products to hospitals in the United States through our dedicated salesforce in our major markets, neuro and vascular. Our sales representatives and sales managers generally have substantial medical device experience and market our products directly to a variety of specialist physicians engaged in the treatment of vascular disorders, who are the end users of our products and significantly influence hospital buying decisions relating to medical devices. We are focused on developing strong relationships with specialist physicians and devote significant resources to training and educating physicians in the use and benefits of our products. The principal specialist physicians in our two target end markets include:

- Neuro: Interventional neuroradiologists, neurosurgeons and interventional neurologists.
- Vascular: Interventional radiologists, vascular surgeons and interventional cardiologists.

In addition to our direct sales organizations, we work with distributors in certain geographic areas where we have determined that selling through distributors is likely to be more effective. The largest market where we sell our products through a distributor is Japan, with Medico's Hirata Inc. as our distributor.

Our direct sales have been, and we anticipate will continue to represent, a majority of our revenues. In 2018, direct sales accounted for approximately 82% of our revenue, with the balance generated by independent distributors that sell our products outside of the United States.

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Backlog

We typically accept and ship orders on the day purchase orders are received or the next business day. Furthermore, if requested, we generally permit customers to cancel or reschedule without penalty. As a result, we do not believe that our backlog at any particular time is material, nor is it a reliable indication of future revenue.

Reimbursement

In the United States, hospitals are the purchasers of our products. Hospitals in turn bill various third-party payors, such as Medicare, Medicaid and private health insurance plans, for the total healthcare services required to treat the patient. Government agencies and some other payors determine whether to provide coverage for a particular procedure and to reimburse hospitals for inpatient treatment at a fixed rate based on the Medicare severity diagnosis-related group ("MS-DRG") as determined by the U.S. Centers for Medicare and Medicaid Services ("CMS"). The fixed rate of reimbursement is generally based on the patients' diagnosis and the procedure performed, and is unrelated to the specific medical device used in that procedure. Medicare rates for the same or similar procedures vary due to geographic location, nature of facility in which the procedure is performed (i.e., teaching or community hospital) and other factors. Private payors vary in their coverage and payment policies. While some may look to coverage and payment by Medicare as a guide, most formulate their own coverage and payment policies.

Some payors may deny reimbursement if they determine that the device used in a treatment was unnecessary, not cost-effective, or used for a non-approved indication. We cannot assure you that government or private third-party payors will cover and reimburse the procedures performed using our products in whole or in part in the future or that payment rates will be adequate.

Outside the United States, market acceptance of medical devices depends partly upon the availability of reimbursement within the prevailing healthcare payment system. Reimbursement levels vary significantly by country, and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. A small number of countries may require us to gather additional clinical data before recognizing coverage and reimbursement for our products. It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

The increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in international markets will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of insurers and managed care organizations, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, medical device reimbursement policies and pricing in general. Our ability to achieve market acceptance or significant sales volume will depend in large part on the availability of coverage and the level of reimbursement for procedures performed using our products under healthcare payment systems in such markets.

All third-party reimbursement programs, whether government funded or insured commercially, whether in the United States or internationally, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, review and analysis of claims, encouragement of and incentives for maintaining healthier lifestyles, and exploration of more cost-effective methods of delivering health care. These types of programs and legislative or regulatory changes to reimbursement policies could potentially limit the amount which healthcare providers may be willing to pay for medical devices.

Competition

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with a number of manufacturers and distributors of neuro and vascular medical devices. Our most notable competitors are Boston Scientific, Johnson & Johnson, Medtronic, Stryker and Terumo. All of these competitors are large, well-capitalized companies with longer operating histories and greater resources than we have. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We also compete with a number of smaller medical device companies that have single products or a limited range of products. Some of

our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers, group purchasing organizations, and third-party payors;
- more established distribution networks;

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- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We compete primarily on the basis that our products are able to treat patients with neuro and vascular diseases and disorders safely and effectively. Our continued success depends on our ability to:

- develop innovative, proprietary products that can cost-effectively address significant clinical needs;
- continue to innovate and develop scientifically advanced technology;
- obtain and maintain regulatory clearances or approvals;
- demonstrate efficacy in Penumbra-sponsored and third-party clinical trials and studies;
- apply technology across product lines and markets;
- attract and retain skilled research and development and sales personnel; and
- cost-effectively manufacture and successfully market and sell products.

Intellectual Property

Our success depends in part on our ability to protect our proprietary technology and intellectual property and operate without infringing the patents and other proprietary rights of third parties. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. We do not have any material licenses to any technology or intellectual property rights. Our subsidiary, MVI Health Inc. (“MVI”), currently has an exclusive license granted by Sixense Enterprises Inc. (“Sixense”) for Sixense’s intellectual property in the fields of healthcare and wellness.

As of December 31, 2018, we owned and/or had rights to 90 issued patents globally, of which 29 were U.S. patents. As of December 31, 2018, we owned and/or had rights to 29 pending patent applications, of which seven were patent applications pending in the United States. Subject to payment of required maintenance fees, annuities and other charges, nine of our issued patents are currently expected to expire between 2025 and 2026; five of these patents relate to components of the Penumbra System and the Indigo System, one of these patents relates to methods performed by the former Apollo System, and three of these patents relate to components of devices that have not been commercialized. An additional four of our issued patents, which relate to components of devices that have not been commercialized, are expected to expire between 2026 and 2027. Thirteen of our issued patents, which relate to components of the Penumbra Coil 400, Ruby Coil System and Smart Coil System, are currently expected to expire between 2029 and 2037. Four patents pertaining to the 3D Revascularization Device are projected to expire between 2032 and 2034. Nineteen patents that pertain to products that have not yet been commercialized are projected to expire between 2028 and 2036. Some of our pending patent applications pertain to components and methods of use associated with currently commercialized products. Our pending patent applications may not result in issued patents and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future products or provide us with any competitive advantage. [See the section titled “Risk Factors-Risks Related to Our Intellectual Property” for additional information.]

Additionally, we own or have rights to trademarks or trade names that are used in our business and in conjunction with the sale of our products, including 15 U.S. trademark registrations and 76 foreign trademark registrations as of December 31, 2018. Included in the registered trademarks is a mark with our company name and logo.

We also seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our proprietary information.

Government Regulation

Our products are medical devices subject to extensive and ongoing regulation by the FDA under the FD&C Act and its implementing regulations, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries under other statutes and regulations. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage,

record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, pricing and discounts, post-marketing surveillance

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and interactions with healthcare professionals. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of Warning letters, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

United States

FDA's Premarket Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance, unless it is exempt, or a premarket approval ("PMA") from the FDA. Medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the FD&C Act, such as provisions that relate to adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class I devices are classified as exempt from premarket notification under Section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, postmarket surveillance, patient registries, and guidance documents. A manufacturer may be required to submit to the FDA a premarket notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA application. However, there are some Class III devices for which the FDA has not yet called for a PMA. For these devices, the manufacturer must submit a premarket notification and obtain 510(k) clearance in order to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order to assure that they are used in a safe and effective manner.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a premarket notification must be submitted to the FDA at least 90 days before we intend to market a device, and we must receive 510(k) clearance from the FDA before we actually market the device. The Medical Device User Fee Amendments ("MDUFA") performance goals for a traditional 510(k) clearance is 90 working days. As a practical matter, however, clearance often takes longer, because the review clock is paused by the FDA to allow time to resolve any questions the FDA may have on the 510(k). To demonstrate substantial equivalence, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or different technological characteristics and the information in the premarket notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class III.

There are three types of 510(k)s: traditional, special and abbreviated. Special 510(k)s are typically for devices that are modified and the modification needs a new 510(k) but does not affect the intended use or alter the fundamental scientific technology of the device. Abbreviated 510(k)s are for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review, and the FDA intends to process special 510(k)s within 30 days of receipt.

Premarket Approval Pathway

A PMA application under section 515 of the FD&C Act must be submitted to the FDA for Class III devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA application process is much more demanding than the 510(k) premarket notification process. A PMA is based on a determination by FDA that the PMA application

contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making

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process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation ("QSR"). The FDA also may inspect one or more clinical sites to assure compliance with the FDA's regulations.

Upon completion of the PMA application review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA application is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required for 510(k) clearance. In the United States, for significant risk devices, these trials require submission of an application for an Investigational Device Exemption ("IDE") to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of FDA's IDE regulations and be approved by an IRB at the clinical trials sites. We, the FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Sponsors of clinical trials of devices are required to register with clinicaltrials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is made public as part of the registration.

Ongoing Regulation by the FDA

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for un-cleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
-

corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health; and

- post market surveillance regulations, which apply to certain Class II or Class III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or possibly a PMA. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new PMA application or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMA applications.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, the California Department of Health Services ("CDHS") requires us to register as a medical device manufacturer within the state. Because of this, the FDA and the CDHS inspect us on a routine basis for compliance with the QSR. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. We have undergone and expect to continue to undergo regular QSR inspections in connection with the manufacture of our products at our facilities. Further, the FDA requires us to comply with various FDA regulations regarding labeling. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

The Medical Device Reporting laws and regulations require us to provide information to the FDA when we receive or otherwise become aware of information that reasonably suggests our device may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

We are also subject to other federal, state and local laws, and regulations relating to safe working conditions, laboratory, and manufacturing practices.

Regulatory Inspections

We are subject to periodic inspections by the FDA and other regulatory entities, such as a European Notified Body, related to the regulatory requirements that apply to medical devices designed and manufactured, and clinical trials sponsored, by us. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or Form FDA 483. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we would be required to respond in writing, and would be required to undertake corrective and/or preventive or other actions in order to address the FDA's or other

regulators' concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

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European Union

Our products are regulated in the European Union as medical devices per the European Union Directive (93/42/EEC), also known as the Medical Device Directive (the "MDD"). An authorized third party, also called a Notified Body, must approve products for CE marking. The CE mark is contingent upon continued compliance to the applicable regulations and the quality system requirements of the ISO 13485 standard.

The new European Medical Devices Regulation (the "EU MDR"), which was published in May 2017 with a transition period of three years, replaces the MDD. Starting May 2020, the new EU MDR will apply and no new applications under the previous directives will be permitted. During the said three-year transition period, we will need to update our technical documentation and other quality management system processes to meet the new EU MDR requirements. Under the new EU MDR requirements, CE certificates issued under the previous directives prior to May 2020 will remain valid in accordance with their term, beyond the expiration of the transition period, however certain limitations set forth in the EU MDR, such as the need to use classifications that are different from the previous directives, would apply. We do not expect such limitations to have any material impact on our ability to supply our products to the market in the region covered by the EU MDR.

Other Regions

Most major markets have different levels of regulatory requirements for medical devices. Modifications to the cleared or approved products may require a new regulatory submission in all major markets. The regulatory requirements, and the review time, vary significantly from country to country. Products can also be marketed in other countries that have minimal requirements for medical devices.

Fraud and Abuse and Other Healthcare Regulation

Anti-Kickback Statute

We are subject to various federal and state healthcare laws, including, but not limited to, anti-kickback laws. In particular, the federal Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for the furnishing or arranging for a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs, such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term "remuneration" expressly includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value.

There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the federal Anti-Kickback Statute. These statutory exceptions and safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the federal Anti-Kickback Statute was amended under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 ("Affordable Care Act"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Affordable Care Act provides that 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 which is discussed below. Penalties for violations of the anti-kickback statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs, and the curtailment or restructuring of operations. Various states have adopted laws

similar to the federal Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors. In addition, many foreign jurisdictions in which we operate have similar laws and regulations.

Federal Civil False Claims Act. The federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim to, or the knowing use of false statements to obtain payment from or approval by, the federal government. Suits filed under the federal civil False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as “relators” or,

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more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a case brought under the federal civil False Claim Act. If an entity is determined to have violated the federal civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have adopted laws similar to the federal civil False Claims Act, and many of these state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government.

Federal Civil Monetary Penalties Statute. The federal Civil Monetary Penalties Statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Sunshine Act. The Affordable Care Act also included a provision, commonly referred to as the Sunshine Act. This provision requires that any manufacturer of a covered device that provides payment or other transfer of value to a physician or teaching hospital, or to a third party at the request of a physician or teaching hospital, must submit to CMS information about the payment or other transfer of value annually, with the reported information to be made public on a searchable website. Similar laws have been enacted in foreign jurisdictions, including France.

Foreign Corrupt Practices Act and Anti-Bribery Laws. The Foreign Corrupt Practices Act ("FCPA") prohibits U.S. companies and their representatives from offering or making payments to foreign officials for the purpose of securing a business advantage. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign government official for purposes of the FCPA. Similar anti-bribery laws are in effect in many of the countries in which we operate.

Health Insurance Portability and Accountability Act of 1996. The federal Health Insurance Portability and Accountability Act ("HIPAA") created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA and its implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information.

The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included an expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Among other things, HITECH created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Employees

As of December 31, 2018, we had approximately 2,200 employees worldwide. None of our U.S. employees are represented by a collective bargaining agreement. Some of our employees outside of the United States are subject to mandatory, industry-specific collective bargaining agreements or the protections of statutory works councils as required by local law. We have never experienced a work stoppage. We believe our employee relations are good.

Facilities

We maintain approximately 295,000 square feet of research and development, manufacturing and administrative facilities in six buildings at our campus in Alameda, California. The leases for these six buildings expire in 2029 to 2031, subject to our option to renew certain leases for an additional five to fifteen years. From time to time through December 31, 2025, if any space in any of the buildings located in the same business park as our campus becomes vacant, that space will be added to the lease. The maximum additional space that could be added under this provision of the lease as of December 31, 2018, is approximately 100,000 square feet. The Company has a right of first offer to

lease any space that becomes available after such date. We also lease approximately 20,000 square feet of warehouse space in Livermore, California. The leases for the warehouse space expire in 2020 to 2022.

On September 17, 2018, we entered into a lease for approximately 160,000 square feet to serve as a manufacturing facility in Roseville, California. The lease is for a fifteen year term, commencing upon substantial completion of improvements to the

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property which we anticipate will happen within the next two years. We have the option to renew the lease for an additional five to ten years.

We also lease office and warehouse space in Germany, Italy, Australia, and Brazil. The offices in Germany and Australia support our direct sales operations in Europe and Australasia, respectively, the office in Brazil supports our Latin America marketing efforts through our distribution partners, and the offices in Italy support the operations of Crossmed S.p.A., our wholly-owned subsidiary in Italy, including supporting our direct sales operations in Italy, San Marino, Vatican City, and Switzerland. We also warehouse and distribute finished products to our international customers utilizing a third-party logistics provider in the Netherlands.

Legal Proceedings

From time to time, we are subject to other claims and assessments in the ordinary course of business. We are not currently a party to any such litigation matter that, individually or in the aggregate, is expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC. Our website address is www.penumbrainc.com. Information on our website is not part of this report. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

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ITEM 1A. RISK FACTORS.

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-K as well as our other publicly available filings with the SEC.

Business Risks

We have a limited operating history and may not be able to sustain or grow our profitability or generate positive cash flows from operations.

We were founded in 2004 and did not generate any revenue until 2007. Moreover, while we have successfully developed, obtained regulatory clearance or approval for, and introduced a number of products in the neuro market since 2007, we first introduced products in the peripheral vascular and neurosurgical markets in 2013 and 2014, respectively. Accordingly, we only have a limited operating history upon which investors can evaluate our business and prospects, and this limited operating history may not be indicative of our future results. We incurred operating losses in 2016 and 2018. We can give no assurance that we will be profitable or cash flow positive in the future. Our sales, general and administrative expenses have increased, and we expect that they will continue to increase, to support our past and anticipated future growth. We have also expended significant amounts on research and development to develop our products, and we expect to continue to do so. We also expend significant amounts on maintaining inventory levels of raw materials, components and finished products to meet anticipated customer demand. In addition, our coil products are sold on a consignment basis, which requires us to expend significant amounts on inventory that is placed at many customer locations. Our ability to sustain our growth and profitability and operate cash flow positive may be influenced by many factors, including:

- our ability to achieve and maintain market acceptance of our products;
- unanticipated problems and additional costs relating to the development and testing of new products;
- our ability to introduce, manufacture at scale, build new inventory and commercialize new products;
- our ability to produce sufficient quantities of our products to meet demand;
- the impact of competition;
- the timing and impact of market and regulatory developments;
- our ability to expand into new markets;
- pricing pressure from competitors;
- the availability and adequacy of third-party reimbursement for procedures in which our products are used; and
- our ability to obtain and maintain adequate intellectual property protection for our products and technologies.

If we encounter difficulties with any of the foregoing or unexpected expenses, it could materially adversely affect our business, results of operations, financial condition or cash flows.

Our existing products may be rendered obsolete and we may be unable to effectively introduce and market new products or may fail to keep pace with advances in technology.

The medical device market is characterized by rapidly advancing technology. Our success depends, in part, on our ability to anticipate technological advancements and competitive innovations and introduce new products to adapt to these advancements and innovations. To compete in the marketplace, we have made, and we must continue to make, substantial investments in new product development, whether internally through research and development or externally through licensing or acquisitions. We can give no assurance that we will be successful in identifying, developing or acquiring, and marketing new products or enhancing our existing products. In addition, we can give no assurance that new products or alternative treatment techniques developed by competitors will not render our current or future products obsolete or inferior, technologically or economically.

The success of any new products that we develop or acquire depends on achieving and maintaining market acceptance. Market acceptance for our current and new products could be affected by a number of factors, including:

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- our ability to market and distribute our products effectively;
- the availability, perceived efficacy and pricing of alternative products from our competitors;
- the development of new products or alternative treatments by others that render our products and technologies obsolete;
- the price, quality, effectiveness and reliability of our products;
- our customer service and reputation;
- our ability to convince specialist physicians to use our products on their patients; and
- the timing of market entry of new products or alternative treatments.

Our competition may respond more quickly to new or emerging technologies or a changing clinical landscape, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than us or be more successful in attracting potential customers and strategic partners. Given these factors, we cannot assure you that we will be able to continue or increase our level of success. Our failure to introduce new and innovative products in a timely manner, and our inability to maintain or grow the market acceptance of our existing products, could result in permanent write-downs of our inventory and otherwise have a material and adverse effect on our business, results of operations, financial condition or cash flows.

Delays in product introductions could adversely affect our business, results of operations, financial condition or cash flows.

The medical device market is highly competitive and designs change often to adjust to shifting market preferences and other factors. Therefore, product life cycles are relatively short. As a result, any 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 launch, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could materially adversely affect our business, results of operations, financial condition or cash flows.

We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with a number of manufacturers and distributors of neuro and vascular devices. Our most notable competitors are Boston Scientific, Johnson & Johnson, Medtronic, Stryker and Terumo. All of these competitors are large, well-capitalized companies with longer operating histories and greater resources than us. We also compete with a number of smaller medical device companies that have a single product or a limited range of products. Our competitors may be able to spend more on product development, marketing, sales and other product initiatives, or be more focused in their spending and activities, than we can. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers, group purchasing organizations and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We compete primarily on the basis that our products are able to treat patients with neurovascular and vascular diseases and disorders safely and effectively, with improved outcomes and procedural cost savings. Our continued success depends on our ability to:

- develop innovative, proprietary products that can cost-effectively address significant clinical needs;
- continue to innovate and develop scientifically advanced technology;

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- obtain and maintain regulatory clearances or approvals;
- demonstrate efficacy in Penumbra-sponsored and third-party clinical trials and studies;
- apply technology across product lines and markets;
- attract and retain skilled research and development and sales personnel; and
- cost-effectively manufacture and successfully market and sell products.

We cannot assure you that we will be able to compete effectively on the basis of these factors. Additionally, our competitors with greater financial resources could acquire or develop new technologies or products that effectively compete with our existing or future products. If we are unable to effectively compete, it would materially adversely affect our business, results of operations, financial condition and cash flows.

Risks Related to our Controlling Interest in MVI Health Inc.

In 2017, we and Sixense formed MVI as a joint venture to explore healthcare applications using virtual reality technology, with each party holding 50% of the issued and outstanding equity of MVI. On August 31, 2018, we purchased an additional 40% of the equity interest in MVI from Sixense for an initial cash purchase price of $20.0 million, excluding additional contingent consideration relating to anti-dilution protection provided to Sixense. We now own a 90% controlling interest in MVI and Sixense retains the remaining 10% minority interest.

Our company is experienced in and has a strong history of bringing technology to healthcare markets. While we are familiar with the healthcare markets that we plan to target initially, we do not have extensive experience in the virtual reality field and are relying on new hires and consultants with expertise in the field. Apart from funds we have invested to date to purchase our interest in MVI, we expect to potentially invest additional funds to fund research and development at MVI, to establish manufacturing operations, to hire dedicated sales and marketing personnel and to commercialize products. We consolidate MVI's financial results into our consolidated financial statements, so losses at MVI could have a materially adverse effect on our business, results of operations, financial condition or cash flows. We can give no assurance that MVI will successfully develop any products or that, if developed, its products will be successfully introduced and accepted by customers. In addition, MVI has a limited operating history. To date, its efforts have been focused on developing products that will bring virtual reality technology to the healthcare field. We have not yet determined the appropriate business model for MVI, which may take time to develop and may not be successful. MVI's ability to operate successfully may be influenced by many factors, including:

- its inability to develop new products and content;
- unanticipated problems and additional costs relating to the development and testing of new products;
- ability to install, set up and service new customers;
- its ability to achieve and maintain market acceptance;
- its reliance on technology licensed from Sixense;
- its possible reliance on a limited number of suppliers for key components of the products it develops;
- establishing an appropriate program for compliance with regulations related to the privacy and security of individually-identifiable patient information, including but not limited to HIPAA;
- its ability to introduce, manufacture at scale, build new inventory and commercialize new products;
- its ability to produce sufficient quantities of products to meet demand;
- the impact of competition;
- the timing and impact of market and regulatory developments, including its ability to obtain any required FDA approvals or clearances;
- its ability to expand into new markets; and
- its ability to obtain and maintain adequate intellectual property protection for its products and technologies.

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Our future growth depends, in part, on our ability to further penetrate our current customer base and increase the frequency of use of our products by our customers.

We will need to continue to make specialist physicians and other hospital staff aware of the benefits of our products to generate increased demand and frequency of use, and thus increase sales to our hospital customers. Although we are attempting to increase the number of patients treated with procedures that use our products through our established relationships and focused sales efforts, we cannot provide assurance that our efforts will increase the use of our products. If we are unable to increase the frequency of use of our products by specialist physicians, this could materially adversely affect our business, results of operations, financial condition or cash flows.

Our future growth depends, in part, on significantly expanding our user base to include additional specialist physicians and other healthcare professionals in both our existing and future target end markets.

Currently, the primary users of our products are specialist physicians, including interventional neuroradiologists, neurosurgeons, interventional neurologists, interventional radiologists, interventional cardiologists and vascular surgeons. We may enter new target end markets with different users in the future. Our revenue growth will depend in part on our ability to convince specialist physicians and other healthcare professionals in our existing and future target end markets of our products' efficacy, to educate them in the proper use of our products and to sell our products to their affiliated hospitals or other organizations. Convincing specialist physicians and other healthcare professionals to use new products and to dedicate the time and energy necessary for adequate education in the use of our products is challenging, especially in new markets where treatments using our products are not established. Expanding our customer base in existing or new target end markets may require, among other things, additional clinical evidence supporting patient benefits, training in a manner to which we are not accustomed, or other resources that we do not readily have available or are not cost effective for us to provide. If we are unable to convert specialist physicians or other healthcare professionals in existing or new target end markets to the use of our products, our sales growth will be limited, which could materially adversely affect our business, results of operations, financial condition or cash flows.

The marketing and sales of our products require a significant amount of time and expense and we may not have the resources to successfully market and sell our products, which would adversely affect our business and results of operations.

The marketing and sales of our products requires us to invest in training and education and employ a salesforce that is large enough to interact with the specialist physicians and others who use our products. Entering new markets also requires a significant amount of time and expense in order to identify and establish relationships with key opinion leaders among the specialist physicians or others who may use our products in those markets. We may not have adequate resources to market and sell our products successfully against larger competitors. For example, when we began selling in the peripheral vascular market in 2013, we did not have a dedicated direct peripheral vascular sales team and our neuro sales team was required to dedicate a portion of its efforts to the sales of our peripheral vascular products. We subsequently expended significant sums to develop a direct salesforce focused on peripheral vascular product sales. If we do not have adequate resources to market and sell our products effectively, or cannot otherwise market and sell our products successfully, it could materially adversely affect our business, results of operations, financial condition or cash flows.

Third-party reimbursement may not be available or adequate for the procedures in which our products are used.

Our ability to commercialize new products successfully in both the United States and international markets depends in part on the availability of, and hospitals' and other customers' ability to obtain, adequate levels of third-party reimbursement for the procedures in which our products are used. In the United States, the cost of medical care is funded, in substantial part, by government insurance programs, such as Medicare and Medicaid, and private and corporate health insurance plans. Third-party payors may deny reimbursement if they determine that a device used in a procedure has not received appropriate FDA or other governmental regulatory clearances or approvals, is not used in accordance with cost-effective treatment methods as determined by the payor, or is experimental, unnecessary or inappropriate. Our ability to commercialize our products successfully will depend, in large part, on the extent to which adequate reimbursement levels for the cost of their use are obtained from government authorities, private health

insurers and other organizations, such as health maintenance organizations. Further, healthcare in the United States and international markets is also being affected by economic pressure to contain reimbursement levels and costs. Changing reimbursement models either domestically or internationally could materially adversely affect our business, results of operations, financial condition or cash flows.

We have generated a significant portion of our revenue and revenue growth from a limited number of product families, and our revenue and business prospects would be adversely affected if sales of any of these product families were to decline.

We have generated most of our revenue and revenue growth from a limited number of product families. If any one or more of these product families were adversely affected because of regulatory, third-party reimbursement or intellectual property

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issues or any other reason, or if one of our competitors introduced one or more products that specialist physicians believe are superior to our products, our revenue from one of these product families could decline. A significant decline in our sales of any of these product families could also negatively impact our financial condition and our ability to conduct product development activities, and therefore negatively impact our business prospects.

We must maintain and further develop relationships with specialist physicians. If specialist physicians do not recommend and endorse, or use, our products or if our relationships with specialist physicians deteriorate, our products may not be accepted or maintain acceptance in the marketplace, which would adversely affect our business and results of operations.

Our products are sold to hospitals for use by specialist physicians practicing at their facilities. In order for us to sell our products, specialist physicians must recommend and endorse them for the hospital to purchase them, and must use them in treating their patients to generate follow-on sales. We may not obtain the necessary recommendations or endorsements for new products from specialist physicians, nor may we be able to maintain the current or future level of acceptance and usage of our products. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy and cost-effectiveness of our products compared to products of our competitors or treatments that do not use our products, and on training specialist physicians in the proper application and use of our products. We invest in significant training and education of our sales representatives and specialist physicians to achieve market acceptance of our products, with no assurance of success. If we are not successful in obtaining and maintaining the recommendations or endorsements of specialist physicians for our products, if specialist physicians prefer our competitors' products or other alternative treatments that do not use our products, or if our products otherwise do not gain or maintain market acceptance, our business could be adversely affected.

In addition, the research, development, marketing and sales of our products are dependent, in part, upon our working relationships with specialist physicians. We rely on them to provide us with knowledge and feedback regarding our products and the marketing of our products. If we are unable to develop or maintain strong relationships with specialist physicians and receive their advice and input, the development and marketing of our products could suffer, which could materially adversely affect our business, results of operations, financial condition or cash flows.

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. If we are unable to achieve or 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 and we may be unable to maintain profitable operations.

We cannot be certain that we will be able to manufacture our products in high volumes at commercially reasonable costs.

We currently maintain our manufacturing operations at our campus in Alameda, California. We currently produce substantially all of our products at this facility, and we do not currently have redundant facilities. We recently signed a lease for additional space in Roseville, California, which we anticipate will include space to be used primarily for manufacturing, but we can give no assurance that this space will be adequate for our future needs. We may need to expend significant capital resources and further increase the size of our manufacturing capabilities as we grow our business. We could, however, encounter problems related to:

- capacity constraints;
- production yields;
- quality control;
- equipment availability; and
- shortages of qualified personnel.

Our continuous product innovation limits our ability to identify and implement manufacturing efficiencies. Failure to do so may reduce our ability to manufacture our products at commercially reasonable costs. If we are unable to manufacture our products in high volumes at commercially reasonable costs, it could materially affect our ability to adequately increase production of our products and fulfill customer orders on a timely basis, which could have a material adverse effect on our business, results of operations, financial condition or cash flows.

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We are required to maintain high levels of inventory, which consume a significant amount of our working capital and could lead to permanent write-downs or write-offs of our inventory.

We maintain a significant inventory of raw materials, components and finished goods, which subjects us to a number of risks and challenges. Our hospital customers typically maintain only small quantities of our products at their facilities, so as products are used, they order replacements that typically require prompt delivery. As a result, we must maintain sufficient levels of finished goods to permit rapid shipment of products following receipt of a customer order. In turn, we must also maintain a sufficient supply of raw materials and components inventory to permit rapid manufacturing and re-stocking of finished goods. Furthermore, our coil inventory is supplied to hospital customers on a consignment basis, which means that it is classified as part of our inventory for financial reporting purposes but is maintained at the hospital location until it is used. We have built, and will continue to build, a significant inventory of coils in order to support the introduction of and to provide adequate consignment stock for our new and existing coil products.

Maintaining a significant inventory of raw materials, components and finished goods, including coils, consumes a significant amount of our working capital. This working capital could be used for other purposes, such as research and development or sales and marketing activities. As we grow our business, we may need substantial additional capital to fund higher levels of inventory, which may materially adversely affect our liquidity or result in dilution to our stockholders if we sell additional equity securities or leverage if we raise debt capital to finance our working capital requirements.

Maintaining a significant inventory of raw materials, components and finished goods, including coils, also subjects us to the risk of inventory excess and obsolescence, which may lead to a permanent write-down or write-off of our inventory. While in inventory, our components and finished goods may become obsolete, in these circumstances we would write-off our inventory and may be required to expend additional resources or be constrained in the amount of end product that we can produce. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire, resulting in a decrease in value and potentially a permanent write-down of our inventory. In the event that a substantial portion of our inventory becomes obsolete, it could materially adversely affect our results of operations.

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

Manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity and adverse competitive pressure. While we have had product recalls, they have all been voluntary, based on our own internal safety and quality monitoring and testing data, and none of our past product recalls has been material. The circumstances giving rise to recalls are, however, unpredictable, and any future recalls of existing or future products could materially adversely affect our business, results of operations, financial condition or cash flows.

The medical device industry has historically been subject to extensive litigation over product liability claims. There are high rates of mortality and other complications associated with some of the medical conditions suffered by the patients whom specialist physicians use our devices to treat, and we may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, health-care providers or others purchasing or using our products, even if our products were not the actual cause of such injury or death. 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, results of operation, financial condition or cash flows.

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 materially adversely affect 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

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result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

Our products are continually the subject of clinical trials conducted by us, our competitors, or other third parties, the results of which may be unfavorable, or perceived as unfavorable, and which could materially adversely affect our business, financial condition and results of operations.

As a part of the regulatory process of obtaining marketing clearance or approval for new products and new indications for existing products, as well as to provide specialist physicians with ongoing information regarding the efficacy of our products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Our competitors and third parties 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, or the market’s or regulators’ perception of clinica