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 clinical data, could materially adversely affect our business, results of operations, financial condition or cash flows.

Our future success depends in part upon establishing an interventional stroke care pathway in the United States that integrates the use of endovascular thrombectomy into the treatment of ischemic stroke.

The stroke care pathway in the United States generally begins with emergency responders who are responsible for transporting the patient to a hospital facility. With a small number of exceptions (such as for trauma), emergency responders in the United States generally operate under a protocol that transports patients to the nearest hospital, which decreases the likelihood that the patient will be transported to a stroke center that has a developed stroke team and an interventional approach to the treatment of stroke. Further, there is no agreed upon standard of care among physicians or hospitals regarding the treatment of ischemic stroke patients, and treatment protocols vary according to the particular hospital, often resulting in significant delays and gaps in patients being assessed for and receiving interventional treatment. The absence of a uniform protocol among hospitals and among physicians within the same hospital means that we have to educate each hospital and stroke center about protocols that integrate our products for the treatment of stroke.

We believe that the stroke care system in the United States has not been historically geared towards interventional treatment of stroke due to the absence of clinical evidence that interventional techniques were effective. Specialist physician societies and we and our competitors are making efforts to alter the existing stroke care pathway, but we anticipate that these efforts will take years to be fully successful. The success of these efforts may depend on whether we and our competitors can effectively use recent positive clinical studies to convince specialist physicians that intervention yields superior clinical results relative to cases where intervention is not used.

Establishing an interventional stroke pathway that integrates the use of interventional treatments, including our products, will depend upon many factors, including:

- effectively educating hospitals and specialist physicians about the clinical evidence supporting intervention, as well as the use, benefits and cost-effectiveness of our products;
- improving the speed with which patients are assessed for and receive interventional treatments; and
- the success of legislative efforts aimed at increasing the likelihood that patients are transported to a hospital or stroke center where interventional treatments are available.

Even if these efforts are successful, it may be years before existing systems and care pathways are changed. These factors may make it difficult to grow our business.

Any data that is gathered in the course of clinical trials may be significantly more favorable than the typical results achieved by practicing specialist physicians, which could negatively impact rates of adoption of our products.

Even if the data collected from clinical trials indicates positive results, each specialist physician's actual experience with our products will vary. Clinical trials often involve procedures performed by specialist physicians who are technically proficient and high volume users. Consequently, the results reported in clinical trials may be significantly more favorable than typical results of other users. If specialist physicians' experiences indicate, or they otherwise believe, that our products are not as safe or effective as other treatment options with which they are more familiar, or clinical trial data indicates the same, adoption of our products may suffer, which could materially adversely affect our business, results of operations, financial condition or cash flows.

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Negative publicity regarding our products or marketing tactics by competitors could reduce demand for our products, which would adversely affect sales and our financial performance.

We may experience, from time to time, negative exposure in clinical publications or in marketing campaigns of our competitors. Such publications or campaigns may present negative individual physician experience regarding the safety or effectiveness of our products or may suggest our competitors' products are superior to ours, based on studies or clinical trials conducted or funded by competitors or that involved competitive products.

Our reputation and competitive position may also be harmed by other publicly available information suggesting that our products are not safe. For example, we file adverse event reports under Medical Device Reporting ("MDR") obligations with the FDA that are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity and could harm our reputation and future sales.

Our dependence on key suppliers puts us at risk of interruptions in the availability of our products, which could reduce our revenue and adversely affect our results of operations. In addition, increases in prices for raw materials and components used in our products could adversely affect our results of operations.

We require the timely delivery of sufficient amounts of components and materials to manufacture our products. For reasons of quality assurance, cost effectiveness or availability, we procure certain raw materials and components from a single or limited number of suppliers. We generally acquire such raw materials and components through purchase orders placed in the ordinary course of business, and as a result we may not have a significant inventory of these materials and components and generally do not have any guaranteed or contractual supply arrangements with many of these suppliers. Our reliance on these suppliers subjects us to risks that could harm our business, including, but not limited to, difficulty locating and qualifying alternative suppliers.

Our dependence on third-party suppliers involves several other risks, including limited control over pricing, availability, quality and delivery schedules. Suppliers of raw materials and components may decide, or be required, for reasons beyond our control, to cease supplying raw materials and components to us or to raise their prices. Shortages of raw materials, quality control problems, production capacity constraints or delays by our suppliers could negatively affect our ability to meet our production requirements and result in increased prices for affected materials or components. We may also face delays, yield issues and quality control problems if we are required to locate and secure new sources of supply. While we have not experienced any to date, any material shortage, constraint or delay may result in delays in shipments of our products, which could materially adversely affect our results of operations. Increases in prices for raw materials and components used in our products could also materially adversely affect our results of operations.

In addition, the FDA and regulators outside of the United States may require additional testing of any raw materials or components from new suppliers prior to our use of these materials or components. In the case of a device with clearance under Section 510(k) of the FD&C Act, referred to as a 510(k), we may be required to submit a new 510(k) if a change in a raw material or component supplier results in a change in a material or component supplied that is not within the 510(k) cleared device specifications. If we need to establish additional or replacement suppliers for some of these materials or components, our access to the materials or components might be delayed while we qualify such suppliers and obtain any necessary FDA approvals or clearances. Our suppliers may also be subject to regulatory inspection and scrutiny. Any adverse regulatory finding or action against those suppliers could impact their ability to supply us with raw materials and components for our products.

Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovative approach, creativity, and teamwork fostered by our culture, and our business may be harmed.

We believe that a critical contributor to our success has been our corporate culture, which we believe fosters innovation, teamwork, and a focus on execution, as well as facilitating critical knowledge transfer and knowledge sharing. As we grow, we may find it difficult to maintain these important aspects of our corporate culture, which could limit our ability to innovate and operate effectively. Any failure to preserve our culture could also negatively affect our ability to retain and recruit personnel or execute on our business strategy.

If our facilities were to become inoperable, we would be unable to continue to develop and manufacture our products until we were able to restore full research, manufacturing and administrative capabilities at our facilities or secure a new facility, and as a result, our business would be harmed.

We currently maintain our research and development, manufacturing and administrative operations in buildings located at our campus in Alameda, California, 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

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no assurance that this space will be adequate for our future needs. Alameda is situated on or near earthquake fault lines, and our facilities are built on filled land, which could be prone to liquefaction in a major earthquake. Should one or more of our buildings be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, because of the time required to approve and license a manufacturing facility under FDA and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost profits, but not losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of raw materials and components and manufactured products, may cause specialist physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with those specialist physicians in the future. Consequently, a catastrophic event at our facility could materially adversely affect our business, results of operations, financial condition or cash flows.

To successfully market and sell our products internationally, we must address a number of unique challenges applicable to international markets.

For the years ended December 31, 2018, 2017 and 2016, we derived 34.7%, 34.3% and 33.1%, respectively, of our revenue from international sales. To accommodate our international sales, we have invested significant financial and management resources to develop an international infrastructure that will meet the needs of our customers. We anticipate that a significant portion of our revenue will continue to be derived from sales of our products in foreign markets and that the percentage of our overall revenue that is derived from these markets may continue to increase. This revenue and related operations will continue to be subject to the risks and challenges associated with international operations, including:

- reliance on distributors;
- varying coverage and reimbursement policies, processes and procedures;
- difficulties in staffing and managing international operations from which sales are conducted;
- difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established;
- reduced protection for intellectual property rights in some countries;
- export licensing requirements or restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification, regulatory requirements and legal requirements;
- lengthy payment cycles and difficulty in collecting accounts receivable;
- customs clearance and shipping delays;
- reliance on third-party logistics providers who warehouse and distribute finished products to our international customers;
- pricing pressure in international markets;
- political and economic instability;
- preference for locally produced products
- higher incidence of corruption or unethical business practices; and
- uncertainty around a potential reversal or renegotiation of international trade agreements and partnerships and the imposition of tariffs under the administration of U.S. President Donald J. Trump.

If we are unable to successfully address these challenges, we may not be able to grow our international sales and our results of operations may suffer as a result.

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Over the long term, we intend to grow our business internationally and to do so, we will need to either spend substantial sums to expand or develop direct sales capabilities in existing and new geographic areas or generate additional sales through existing distributors or attract additional distributors.

As a result of our international operations, we are required to comply with tax requirements in multiple jurisdictions, the scope and impact of which may be unclear. Moreover, tax authorities in jurisdictions in which we do business could disagree with tax positions that we take, including, for example, our inter-company pricing policies, or could assert that we owe more taxes than we currently pay due to the level and nature of our activities in such jurisdictions.

The June 2016 referendum by British voters to exit the European Union and the commencement of the official withdrawal process by the United Kingdom government in March 2017 has created uncertainties affecting business operations in the United Kingdom and the European Union. Until the terms of the United Kingdom's exit from the European Union in March 2019 are determined, it is difficult to predict its impact, but it is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our businesses are subject, impact trade between the United Kingdom and the European Union and other parties and create economic uncertainty in the region.

In 2018, the United States imposed tariffs on goods imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional tariffs imposed by the United States on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, could result in an increase in supply chain costs or other pricing pressures that we may not be able to offset or may otherwise adversely impact our results of operations.

We rely on our distributors to market and sell our products in certain international markets.

We have established a direct sales capability in the United States, most of Europe, Canada and Australia, which we have complemented with distributors in Japan and certain other international markets. Sales to distributors represented 18.1%, 18.2% and 17.9% of our revenue in 2018, 2017 and 2016 respectively. Our success outside of the United States, most of Europe, Canada and Australia depends largely upon marketing arrangements with distributors, in particular their sales expertise and their relationships with specialist physicians and affiliated hospitals in their geographic areas. Distributors may terminate their relationship with us, sell competitive products or devote insufficient sales efforts or other resources to our products. We do not control our distributors, and they may not be successful in implementing our marketing plans. In addition, many of our distributors initially obtain and maintain foreign regulatory approval for the sale of our products in their respective countries, and their efforts in obtaining and maintaining regulatory approval may not be as robust as we desire or expect. Our failure to maintain our existing relationships with our distributors, or our failure to recruit and retain additional skilled distributors in existing or new international markets, could have an adverse effect on our operations. If current or future distributors do not perform adequately, or if we lose a significant distributor, such as our Japanese distributor, we may not be able to maintain existing levels of international revenue or realize expected long term international revenue growth. We have also experienced turnover with some of our distributors in the past that has adversely affected sales in the countries in which those distributors operate. Similar occurrences could happen in the future.

Most of our customer relationships outside of the United States are with governmental entities, and we could be materially adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in non-U.S. jurisdictions.

The U.S. Foreign Corrupt Practices Act (the "FCPA"), the United Kingdom Bribery Act, the Chinese Anti-Unfair Competition Law, and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities, and physicians practicing in those systems are considered "government officials." Therefore, our sales to these entities are subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption, and we have operations in certain countries, including Russia and China, where strict compliance with anti-bribery laws may be at variance with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or

criminal acts committed by our employees, distributors or agents. Violations of the FCPA or other anti-bribery laws, or allegations of such violations, could disrupt our business and materially adversely affect our business, results of operations, financial condition or cash flows.

Foreign currency exchange rates may adversely affect our results.

We are exposed to the effects of changes in foreign currency exchange rates, and we have not historically hedged our foreign currency exposure. Approximately 34.7%, 34.3%, and 33.1% of our revenue for the years ended December 31, 2018, 2017 and 2016, respectively, were derived from sales in non-U.S. markets, and we expect sales from non-U.S. markets to

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continue to represent a significant portion of our revenue. For direct sales in our international markets, we are paid by our customers in their local currency, which is primarily euros. For sales to distributors in our international markets, we are paid in either U.S. dollars, euros or Japanese yen, with some sales being denominated in other currencies. Therefore, when the U.S. dollar strengthens relative to the euro, yen or other local currency, our U.S. dollar reported revenue from non-U.S. dollar denominated sales will decrease, or we will need to increase our non-U.S. dollar denominated prices, which may not be commercially practical. Conversely, when the U.S. dollar weakens relative to the euro, yen or other local currency, our U.S. dollar reported expenses from non-U.S. dollar denominated operating costs will increase. Global markets and foreign currencies, including the Euro and the British Pound, were adversely impacted, as a result of the June 23, 2016 referendum by British voters to exit the European Union and volatility in foreign currencies is expected to continue as the United Kingdom negotiates and executes its exit from the European Union. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, results of operations, financial condition or cash flows.

We have experienced rapid growth in recent periods, and if we fail to manage our growth effectively, our business and results of operations may suffer.

We have significantly expanded our overall business, research and development, customer base, product portfolio, employee headcount and operations in recent periods. We have also established new operations in other countries. We have increased our total number of full-time employees from 1,100 as of December 31, 2015, to approximately 2,200 as of December 31, 2018. Our expansion has placed, and our expected future growth will continue to place, a significant strain on our managerial, operational, product development, sales and marketing, administrative, financial and other resources.

We plan to continue to increase our salesforce. Our experience has been that it takes at least six months, and often longer, before new sales personnel generate enough sales to cover their costs, resulting in increased costs without offsetting revenue during periods in which we are increasing the size of our salesforce.

More systems, facilities, processes and management employees are needed to allow us to continue to grow successfully. We are expanding and renovating our existing corporate facilities in Alameda, California, and a new facility in Roseville, California, driven by our need to expand the space available for our product development and test capacities, as well as our need for additional information technology and office space. The expansion and renovation of our corporate facilities entail risks that could cause disruption in the operations of our business. Such risks include potential interruption in data flow; unforeseen construction, scheduling, engineering, environmental, or geological problems; and unanticipated cost increases. To meet anticipated demand for our products, we will also have to continue to buy additional equipment and hire additional research and development and manufacturing employees, including quality control personnel and other personnel involved in the production process. This expansion could result in operating difficulties including, but not limited to, difficulties in hiring the appropriate number of research and development and manufacturing employees, training and managing an increasing number of employees, delays in production and shipments, manufacturing inefficiencies and employees not working at capacity. If we do not adapt to meet these evolving challenges and if we are unable to manage our growth successfully, it could have a material and adverse effect on our business, results of operations, financial condition or cash flows.

We have experienced rapid growth in the market for our products and we believe this market may not continue to grow sustainably at these rates.

Annual revenue from our neurovascular products and vascular products increased by $181.6 million, or 69.0%, over a two-year period from 2016 to 2018. This growth was the result of many factors, including but not limited to continued investment in our sales force and a shift to endovascular treatment as the standard of care in treatment of stroke. We do not expect that the rate of market growth will continue at this pace in the future. As we continue to grow and scale our business, we expect that our growth rates will be more gradual.

We depend on key personnel to operate our business and develop our products, and if we are unable to retain, attract and integrate qualified personnel, our ability to develop and successfully grow our business could be harmed.

We believe that our future success is highly dependent on the contributions of our executive officers, particularly our chief executive officer, as well as our ability to attract and retain highly skilled and experienced sales and marketing, technical and other personnel in the United States and in international markets. Each of these persons' efforts will be

critical to us as we continue to develop our products and business. If we were to lose one or more of our key employees, including to competitors, we may experience difficulties in competing effectively, developing our products and implementing our business strategies.

Our research and development and sales and marketing programs depend on our ability to attract and retain highly skilled technicians, engineers and salespeople. In general, we may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area, where our corporate headquarters, research and development and manufacturing facilities are located. In addition to the

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competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. Although we historically have not had any material difficulty attracting qualified experienced personnel to our company, we could in the future have such difficulties and may be required to expend significant financial resources in our employee recruitment and retention efforts. If we are not able to identify, recruit and retain highly qualified personnel, we may experience constraints that will adversely affect our ability to support our research, development, manufacturing and sales programs, and ultimately our ability to compete. If we are unable to identify, recruit and retain qualified salespeople, there could be a delay or decline in the adoption of our products. If key personnel were to leave Penumbra, either to join our competitors or otherwise, we may not be able to attract and retain equally qualified personnel to replace them.

We depend on information technology systems to operate our business, and issues with maintaining, upgrading or implementing these systems, could have a material adverse effect on our business.

We rely on the efficient and uninterrupted operation of information technology systems to process, transmit and store electronic information in our day-to-day operations. All information technology systems are vulnerable to damage or interruption from a variety of sources. Our business has grown in size and complexity; this has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, our information systems and applications require an ongoing commitment of significant resources to maintain, protect, enhance and upgrade existing systems and develop and implement new systems to keep pace with changing technology and our business needs. In 2017, we completed an upgrade to our existing enterprise resource planning ("ERP") software system to perform various functions, and we may implement other upgrades or new systems in the near future including the integration of any acquired businesses or the establishment of new subsidiaries into such systems. These upgrades or system changes entail certain risks, including difficulties with changes in business processes that could disrupt our operations - such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data. During the transitions, we may continue to rely on legacy information systems, which may be costly or inefficient, while the implementation of new initiatives may not achieve the anticipated benefits and may divert management's attention from other operational activities, negatively affect employee morale, or have other unintended consequences. Delays in integration or disruptions to our business from implementation of new or upgraded systems could have a material adverse impact on our financial condition and operating results. Additionally, if we are not able to accurately forecast expenses and capitalized costs related to system upgrades and changes, this may have an adverse impact on our financial condition and operating results.

If the information we rely upon to run our businesses were to be found to be inaccurate or unreliable, if we fail to maintain or protect our information technology systems and data integrity effectively, if we fail to develop and implement new or upgraded systems to meet our business needs in a timely manner, or if we fail to anticipate, plan for or manage significant disruptions to these systems, our competitive position could be harmed, we could have operational disruptions, we could lose existing customers, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, specialist physicians and other health care professionals, have regulatory sanctions or penalties imposed or other legal problems, incur increased operating and administrative expenses, lose revenues as a result of a data privacy breach or theft of intellectual property or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition or cash flows.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology, telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems are vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and

disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent, and our systems could be the target of malware and other cyber-attacks. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. We can give no assurances that these measures and efforts will prevent interruptions or breakdowns. If we are unable to detect or prevent a security breach or cyber-attack or other disruption from occurring, then we could incur losses or damage to our data, or inappropriate disclosure of our confidential information or that of others; and we could sustain damage to our reputation and customer and employee relationships, suffer disruptions to our business and incur increased operating costs including costs to mitigate any damage caused and protect against future damage, and be exposed to additional regulatory

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scrutiny or penalties and to civil litigation and possible financial liability, any of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

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

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

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

The successful use of our products depends, in part, on our ability to educate specialist physicians in the proper use of our products, which may be more complex than competitive products or alternative treatments that do not use our products. If we are unable to educate specialist physicians in the proper use of our products, we may experience a high risk of product liability.

The successful use of our products depends, in part, on our ability to educate specialist physicians in the proper use of our products, which may be more complex than competitive products or alternative treatments that do not use our products. We educate specialist physicians on the proper techniques in using our products to achieve the intended outcome. However, our products may be more complicated to operate than competitive products or alternative treatments that do not use our products. In the event that specialist physicians perceive that our products are complex relative to alternative products or established treatments that do not use our products, we may have difficulty gaining or increasing adoption of our products. Further, we may be unable to provide adequate education on the use of our products to specialist physicians, and some specialist physicians may not be willing to invest the time required to become properly educated on the use of our products. If we are unable to educate specialist physicians to properly use our products, this may lead to inadequate demand for our products and materially adversely affect our business, results of operations, financial condition or cash flows.

If we do not adequately educate specialist physicians on the use of our products, and our products are used incorrectly during procedures, we may also be subject to claims against us by such specialist physicians, their hospitals or their patients. Our business, including our reputation, may consequently be adversely affected by any litigation that may occur based on error in the use of our products, and such litigation could also materially adversely affect our results of operations, financial condition or cash flows.

Regulatory Risks

We are subject to stringent domestic and foreign medical device regulation, which may impede the approval or clearance process for our products, hinder our development activities and manufacturing processes and, in some cases, result in the recall or seizure of previously approved or cleared products.

Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA and by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Manufacturers of medical devices such as us must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging and distribution of medical devices. In addition, medical devices must receive FDA clearance or approval before they can be commercially marketed in the United States. The

FDA may require testing and surveillance programs to monitor the effects of cleared or approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post-marketing programs. Furthermore, most major markets for medical devices outside the United States require clearance, approval or compliance with certain standards and requirements before a product can be commercially marketed. The process of obtaining marketing approval or clearance from the FDA and foreign regulatory agencies for new products could take a significant period of time, require the expenditure of substantial resources, involve rigorous pre-clinical and clinical testing, require changes to our products and result in limitations on the indicated uses

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of our products. We cannot provide assurance that we will receive the required approval or clearance from the FDA and foreign regulatory agencies for future products on a timely basis. Results from pre-clinical studies and early clinical trials may not allow us to predict results in later-stage testing. We cannot be certain that our future clinical trials will demonstrate the safety and effectiveness of any of our future products or will result in clearance or approval to market any of these products. In addition, our development activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. The failure to receive approval or clearance for significant new products on a timely basis could have a material adverse effect on our business, results of operation, financial condition or cash flows.

The FDA and other foreign regulatory entities also conduct periodic inspections of our facilities to determine compliance with the FDA's QSR requirements, MDR regulations and all comparable foreign regulations. Product approvals or clearances by the FDA can be withdrawn, and new product approvals or clearances by the FDA and foreign regulatory bodies can be delayed, due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial approval or clearance of a product. The failure to comply with regulatory requirements or the discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory approvals or clearances, seizures or recalls of products (with the attendant expenses and adverse competitive impact), the banning of a particular device, an order to replace or refund the cost of any device previously manufactured or distributed, operating restrictions and criminal prosecution, as well as decreased sales as a result of negative publicity and product liability claims, all of which could have a material adverse effect on our business, results of operation, financial condition or cash flows.

The implementation of healthcare reform in the United States could have a material adverse effect on our business.

In March 2010, the Patient Protection and Affordable Care Act was enacted into law in the United States (as amended by the Health Care and Education Reconciliation Act, the Affordable Care Act). The Affordable Care Act includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. Specifically, the law imposed a 2.3% excise tax on the sale in the United States of certain medical devices by a manufacturer, producer or importer of such devices starting after December 31, 2012. While this tax was suspended for an additional two-year period commencing January 1, 2018, absent further legislative action, it will be reinstated in 2020. The Affordable Care Act also reduces Medicare and Medicaid payments to hospitals and clinical laboratories, which could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell them. While this legislation is intended to expand health insurance coverage to uninsured persons in the United States, the impact of any overall increase in access to healthcare on sales of our products remains uncertain. Various healthcare reform proposals have also emerged at the state level. In addition, there have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect that the Trump Administration may seek to modify, repeal or otherwise invalidate or vitiate all, or certain provisions of, the Affordable Care Act in the future. The impact of the Affordable Care Act and these proposals could have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we modify our FDA cleared products, we may need to seek and obtain new clearances, which, if not granted, would prevent us from selling our modified products or require us to redesign our products.

A component of our strategy is to continue to modify and upgrade our products that have been cleared by the FDA. The FDA requires device manufacturers to make a determination of whether or not a modification requires a clearance; however, the FDA can review a manufacturer's decision not to submit for additional clearances. Any modifications to an FDA cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. We also cannot provide any assurance that the FDA will agree with our decisions not to seek clearances for particular device modifications. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not

or will not require additional clearances. If the FDA disagrees, and requires new clearances or approvals for any modifications, and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to recall and to stop the manufacturing and marketing of the modified device until we obtain FDA approval or clearance, and we may be subject to significant regulatory fines or penalties, all of which could harm our results of operations and require us to redesign our products.

We may not receive necessary foreign regulatory approvals or clearances or otherwise comply with foreign regulations.

For the years ended December 31, 2018, 2017 and 2016, sales outside the United States accounted for approximately 34.7%, 34.3%, and 33.1%, respectively, of our total sales, and we expect this percentage to increase in future years. Foreign regulatory bodies have established varying regulations. Specifically, the European Union has promulgated rules that require that

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medical device products receive the right to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. Although we have received CE markings for all of the products we currently sell in the European Union, we can give no assurance that we will be able to obtain European Union approval for any of our future products. Our inability or failure, or the inability or failure of our international distributors, to comply with varying foreign regulations or the imposition of new regulations could restrict or, in certain countries, result in the prohibition of the sale of our products, and thereby adversely affect our business, financial condition and results of operations. In addition, our profitability from our international operations may be limited by risks and uncertainties related to economic conditions in these regions, foreign currency fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development, rights to intellectual property and our ability to implement our overall business strategy. Any significant changes in the competitive, political, legal, regulatory, reimbursement or economic environment where we conduct international operations may have a material adverse effect on our business, results of operation, financial condition or cash flows.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Many countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and/or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies recently finalized a new Medical Device Regulation ("EU MDR"), which changes many aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification ("UDI"). Once applicable, the MDR may impose increased compliance obligations for us to access the EU market. The EU MDR becomes effective following a three-year transition period in May 2020 and we, and the Notified Bodies who will oversee compliance to the new EU MDR, face uncertainties in the upcoming years as the EU MDR is rolled out and enforced, creating risks in several areas, including the CE Marking process, data transparency and application review timetables.

We may not be able to meet regulatory quality requirements applicable to our manufacturing process.

We are required to register with the FDA as a device manufacturer and as a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation ("QSR") requirements, which requires manufacturers of medical devices to adhere to certain requirements, including testing, quality control and documentation procedures. In addition, the federal MDR regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury, or has malfunctioned, and if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell products and we undergo periodic inspections by notified bodies to obtain and maintain these certifications. On March 1, 2016, the ISO issued a new Quality Management System ("QMS") standard for medical device manufacturers, ISO 13485:2016. We received certification to ISO 13485:2016 in June 2018. Compliance with this standard is subject to continual review and is monitored through periodic inspections by our notified body. Some foreign countries, most notably Japan and Brazil, have similar requirements or may require inspections of our manufacturing facilities before approving a product for sale in their country. We have decided 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. We received our first MDSAP certification in August 2018. Some of our suppliers are subject to the same or similar scrutiny. If we or our suppliers fail to adhere to QSR, ISO or other regulatory requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances or approvals, recalls or other consequences, which could in turn have a material adverse effect on our business, results of operation, financial

condition or cash flows.

We are subject to periodic inspections by the FDA and other regulatory bodies related to regulatory requirements that apply to medical devices designed and manufactured, and clinical trials sponsored, by us. We have previously received and could in the future receive notices of inspectional observations or deficiencies from the FDA. Any such notices would require us to undertake corrective and preventive actions or other actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses.

We are subject to periodic inspections by the FDA and other regulatory bodies. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we may be required to undertake corrective and preventive actions or other actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and

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could impose additional burdens and expenses. Failure to adequately address the FDA's concerns could expose us to enforcement and administrative actions.

We are subject to federal, state and foreign healthcare laws and regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We are subject to various healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as foreign and state anti-kickback, anti-benefit and false claims laws, as well as state and foreign laws and regulations governing interactions with healthcare professionals and requiring disclosure of payments and interactions with healthcare professionals and state and foreign laws governing the privacy and security of health information in certain circumstances.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operation, financial condition

or cash flows.

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The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. For example, devices cleared under section 510(k) cannot be marketed for any intended use that is outside of the FDA's substantial equivalence determination for such devices. Physicians nevertheless may use our products on their patients in a manner that is inconsistent with the intended use cleared by the FDA. If we are found to have promoted such "off-label" uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Our operations are subject to environmental, health and safety, and data privacy laws and regulations, with which compliance may be costly.

Our business is subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances and wastes. Failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. In addition, environmental laws and regulations could require us to pay for environmental remediation and response costs, or subject us to third party claims for personal injury, natural resource or property damage, relating to environmental contamination. Liability may be imposed whether or not we knew of, or were responsible for, such environmental contamination. The cost of defending against environmental claims, of compliance with environmental, health and safety regulatory requirements or of remediating contamination could materially adversely affect our business, assets or results of operations and, consequently, amounts available for distribution to our stockholders.

Additionally, we are subject to laws and regulations with respect to the collection, use, disclosure, transfer and storage of personal data that we may collect from our employees, consultants or in conjunction with clinical trials. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues that may affect our business. For example, the European Union's General Data Protection Regulation ("GDPR"), which became effective in May 2018, established new, and in some cases more stringent, requirements for data protection in Europe. Under the GDPR, enhanced data protection requirements as well as substantial fines for breaches of personal data will apply and increase our obligations and potential liabilities for the personal data that we process or control. We have modified and will continue to modify our practices in order to comply with these and other requirements, which requires us to incur costs and expenses, and we may face difficulties in complying with all privacy and data protection legal requirements that apply to us now or in the future, as well as financial penalties and liabilities if we are unable to do so. Similar issues could arise as a result of the passage of the California Consumer Privacy Act which becomes effective January 1, 2020.

Regulations and customer demands related to conflict minerals may force us to incur additional expenses and may make our supply chain more complex.

The Dodd-Frank Wall Street Reform and Consumer Protection Act ("the Dodd-Frank Act") imposes disclosure requirements regarding the use in components of our products of "conflict minerals" mined from the Democratic Republic of Congo and adjoining countries, whether the components of our products are manufactured by us or third parties. This requirement could affect the pricing, sourcing and availability of minerals used in the manufacture of components we use in our products. In addition, there are additional costs associated with complying with the disclosure requirements and customer requests, such as costs related to our due diligence to determine the source of any conflict minerals used in our products. Compliance with these requirements could adversely affect the sourcing, supply and pricing of materials used in those products and we may face reputational challenges if we are unable to verify the origins for all "conflict minerals" used in products through the procedures we have implemented.

Risks Related to Our Intellectual Property

We rely on a variety of intellectual property rights, and if we are unable to maintain or protect our intellectual property, our business and results of operations will be harmed.

Our commercial success will depend, in part, on our ability to obtain and maintain intellectual property protection for our products and related technologies both in the United States and elsewhere, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. While we rely primarily upon a combination of patents, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, products and other proprietary technologies, protection derived from patents is relatively limited.

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The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or if any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology.

The patent positions of medical device companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. The standards that the U.S. Patent and Trademark Office ("USPTO") and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act ("Leahy-Smith Act") in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter parties review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire

patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

We may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, business prospects and financial condition.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The medical device industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. Numerous third party patents exist in the fields relating to our products, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our products, components of our products and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;

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- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, selling, using, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products and technology so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If

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securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, including switching the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. Many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective recently. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions. In addition, periodic maintenance fees on our owned and in-licensed patents are due to be paid to governmental patent agencies over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents that may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our licensor to pay annuity fees due to patent agencies on our patents and pending patent applications. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

We currently own 12 trademarks, related to our company name, logo, products and technology, that are registered with the USPTO as well as 38 trademarks registered outside of the United States. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks or names. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential customers in our markets of interest. There is no guarantee we will be able to secure registration for any of our pending trademark applications with the USPTO or comparable foreign authorities. In addition, third parties have registered trademarks similar and identical to our trademarks, and may in the future file for registration of such trademarks. If they succeed in registering or developing

common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries where such third parties have registered such trademarks or obtained such common law rights. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

In addition, we may be involved in litigation or other proceedings to protect our trademark rights associated with our company name or the names used with our products. For example, we are currently opposing the registration of a product name

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on the grounds that the name is confusingly similar to our ACE brand, and that use of the name by a competitor will cause confusion in the marketplace. An adverse decision in such proceeding could have a negative impact on the value of the ACE brand. Any objections we receive from the USPTO, foreign trademark authorities or third parties relating to our pending applications could require us to incur significant expense in defending the objections or establishing alternative names. Names used with our products may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or any product, we may experience a loss in goodwill associated with our brand name, customer confusion or a loss of sales.

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

In addition to patent protection, we also rely on confidential proprietary information, including trade secrets and know-how, to develop and maintain our competitive position. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements with our employees, consultants, collaborators, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreements, such inventions may become assigned to third parties. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

We may also employ individuals who were previously or concurrently employed at research institutions and/or other medical device companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our products, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

It is difficult to forecast future performance, which may cause our financial results to fluctuate unpredictably.

A number of factors over which we have limited or no control may contribute to fluctuations in our financial results, such as:

- variations in revenue due to the unavailability of specialist physicians who use our products during certain times of the year, such as those periods when there are major conferences on conditions they treat or those periods when high volume users of our products take time off of work;

- positive or negative media coverage of our products or the procedures or products of our competitors or our industry;
- publication of clinical trial results or studies by us or our competitors;
- changes in our sales process due to industry changes, such as changes in the stroke care pathway;

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- delays in receipt of anticipated purchase orders;
- delays in customers receiving products;
- performance of our independent distributors;
- our ability to obtain further regulatory clearances or approvals;
- the timing of product development and clinical trial activities, including the pace of enrollment;
- delays in, or failure of, product and component deliveries by our suppliers;
- changes in reimbursement policies or levels;
- the number of procedures performed in any given period using our products, which can sometimes vary significantly between periods;
- customer response to the introduction of new products or alternative treatments, and the degree to we which we are effective in transitioning customers to our products; and
- fluctuations in foreign currency.

In the event our actual revenue and results of operations do not meet our or others' forecasts for a particular period, the market price of our common stock may decline substantially.

We may require additional financing in the future and may not be able to obtain such financing on favorable terms, if at all, which could force us to delay, reduce or eliminate our research and development activities or otherwise harm our business.

Since our initial public offering in September 2015, we have financed our operations primarily through our operations and sales of our equity securities. We are unable to predict the extent of any future operating cash flows or whether we will be able to maintain or grow our profitability. If we require additional financing to continue or expand our operations, for research and development, for acquisitions or for other purposes, we may determine to engage in equity or debt financings or incur other indebtedness. We may not be able to timely secure additional debt or equity financing on favorable terms, or at all. If we raise additional funds through the issuance of equity or convertible debt or other equity-linked securities, our existing stockholders could suffer significant dilution. Any debt financing obtained by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If needed funds are not available in adequate amounts or on acceptable terms from additional financing sources, our business will be materially adversely affected.

By engaging in acquisitions and other business development arrangements, we will incur a variety of costs and may potentially face numerous risks that could adversely affect our business and operations.

We have in the past, and expect in the future, to seek to acquire additional businesses, assets, technologies or products to enhance our business if appropriate opportunities become available. In connection with any acquisitions, we could issue additional equity securities or convertible debt or equity-linked securities, which would dilute our stockholders, cause us to incur substantial debt to fund the acquisitions, or assume significant liabilities.

Acquisitions involve numerous risks, including problems integrating the purchased operations, technologies or products, unanticipated costs and other liabilities, diversion of management's attention from our core businesses, adverse effects on existing business relationships with current and/or prospective customers and/or suppliers, risks associated with entering markets in which we have no or limited prior experience and potential loss of key employees. Acquisitions may also require us to record goodwill and non-amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, and incur write-offs and restructuring and other related expenses, any of which could harm our results of operations and financial condition. If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business and financial condition may be adversely affected.

Fluctuations in our effective tax rate and changes to tax laws may adversely affect us.

As an international company, we are subject to taxation in numerous countries, states and other jurisdictions. Our effective tax rate is derived from a combination of statutory tax rates in the various jurisdictions in which we operate. In preparing our financial statements, our effective tax rate is based on estimates of the amount of tax that will become

payable in each of these jurisdictions. Our effective tax rate may, however, differ from estimates due to numerous factors, including a change in the mix

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of our profitability from country to country and changes in tax laws. The fluctuations in our effective tax rate could have an adverse effect on our business, financial condition and results of operations and cash flows.

Our excess tax benefits and tax deficiencies are required to be recorded in the income statement when stock awards vest or are settled and as discrete items on the tax rate in the period in which they occur. The amount of excess tax benefits can fluctuate from period to period based on the price of our stock, the volume of share-based grants settled or vested, and the fair value assigned to equity awards under U.S. GAAP. For interim reporting purposes, we are required to exclude the excess tax benefits and tax deficiencies from the annual estimated tax rate and not to forecast the potential impact to our rate. As a result, we could experience an effective tax rate significantly different from previous periods or from our expectations.

The Tax Cuts and Jobs Act of 2017 ("the TCJA") was signed into law by President Donald J. Trump on December 22, 2017. This legislation made significant changes to the U.S. Internal Revenue Code, including a reduction in the corporate tax rate, implementation of a territorial tax regime, and limitations on certain corporate deductions and credits. We completed the accounting for the income tax effects of the applicable legislative changes under the TCJA, including but not limited to, the reduction in corporate income tax rate, global intangible low-tax income ("GILTI") inclusion, and the one-time transition tax. The impact of the TCJA reflected in our financial statements is based on our interpretation of the guidance available as of each reporting period. Our accounting for the income tax effects of the TCJA may change as additional interpretive guidance, potential amendments, and technical corrections to the tax reform legislation are released.

In addition, changes in tax law or declines in our underlying profitability may negatively or positively impact our financial outlook of operations, which could lead to a corresponding charge or benefit to income taxes attributable to adjustments to the valuation allowance recorded against our deferred tax assets ("DTAs") on our consolidated balance sheets. The tax charge or benefit resulting from such change in valuation allowance could result with fluctuations in our effective tax rate, and have a material negative impact on our financial condition and results of operations.

Risks Relating to Securities Markets and Investment in Our Common Stock

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and is likely to continue to be volatile. From January 1, 2018 through December 31, 2018 our closing stock price as reported on The New York Stock Exchange ("NYSE") has ranged from $84.60 to $165.95. Stock markets have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, limited trading volume of our stock may contribute to its future volatility. Price declines in our common stock could result from general market and economic conditions, some of which are beyond our control, and a variety of other factors, including any of the risk factors described in this Annual Report on Form 10-K or those that we have not anticipated. These broad market and industry factors may harm the market price of our common stock, regardless of our operating performance, and could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid for such shares. Factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of medical device company stocks;
- changes in operating performance and stock market valuations of other medical device companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our results of operations or fluctuations in our results of operations;

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- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If our executive officers, directors and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their own best interests and not necessarily those of other stockholders.

As of December 31, 2018, our executive officers, directors and holders of 5% or more of our outstanding stock and their affiliates beneficially owned approximately 38.9% of our voting stock in the aggregate. These stockholders, acting together, would be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

A sale of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, 2018, our directors, executive officers and holders of 5% or more of our outstanding stock beneficially owned approximately 38.9% of our outstanding stock in the aggregate. If one or more of them were to sell a substantial portion of the shares they hold, it could cause our stock price to decline.

We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. As of December 31, 2018, approximately 10,200,000 shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Our restated certificate of incorporation, our amended and restated bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law (where we are incorporated), our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;

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- requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and amended and restated bylaws;
- eliminating the ability of stockholders to call and bring business before special meetings of stockholders;
- prohibiting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- dividing our board of directors into three classes so that only one third of our directors will be up for election in any given year; and
- providing that our directors may be removed by our stockholders only for cause.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that could have resulted in a premium over the market price for shares of our common stock.

These provisions apply even if a takeover offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in our and our stockholders' best interests and could also affect the price that some investors are willing to pay for our common stock.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the General Corporation Law of the State of Delaware, our restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

We incur significant costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses as we devote resources to comply with the Securities Exchange Act of 1934, as amended ("the Exchange Act"), the Sarbanes-Oxley Act of 2002 ("the Sarbanes-Oxley Act"), and the Dodd-Frank Act, as well as rules and regulations subsequently implemented by the SEC and the NYSE, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly.

We plan to continue to invest resources to comply with the evolving laws, regulations and standards applicable to public companies, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. Operating as a public company and being subject to these rules and regulations makes it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. As a result, it may be difficult for us to attract and retain qualified members of our board of directors or executive officers.

The costs associated with operating as a public company may decrease our net income or increase any future net loss and may cause us to reduce costs in other areas of our business or increase the prices of our products to offset the effect of such costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Exchange Act, Sarbanes-Oxley Act, and the listing standards of the NYSE. We expect that the requirements of these rules and regulations will continue to increase our

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legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

Our current controls and any new controls that we develop may become inadequate because of changes in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in errors in our financial statements or a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of management evaluations and independent registered public accounting firm audits of our internal control over financial reporting that we include in our periodic reports that are filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NYSE.

As a public company, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required to audit the effectiveness of our internal control over financial reporting. If we identify material weaknesses in our internal controls over financial reporting, if we are unable to assert that our internal control over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and results of operations, and cause a decline in the price of our common stock.

If securities or industry analysts publish inaccurate or unfavorable research about our business or cease publishing research, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock, which may never occur, would provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

An additional valuation allowance against our deferred tax assets could require a charge to earnings, which could result in a negative impact on our results of operations.

Primarily as a result of net operating losses, stock-based compensation, various accruals and reserves, and tax credits, we maintain foreign and domestic DTAs. DTAs reflect an expected benefit to be realized in the future that may be used to reduce the amount of tax that we would otherwise be required to pay in future periods. DTAs are reduced by a valuation allowance when it is more likely than not that the future realization of all or some of the DTAs will not be achieved. Valuation allowances related to DTAs can be affected by changes to tax laws, statutory tax rates, future taxable income levels and input from our tax advisors or regulatory authorities. With the adoption of Accounting Standard Update (“ASU”) 2016-09 during the year ended

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December 31, 2016, we created additional domestic DTAs in the balance sheet and recognized excess tax benefits in our provision for income taxes. At this time, we consider it more likely than not that we will have sufficient taxable income in the future that will allow us to realize the benefits of the domestic DTAs we maintain as of December 31, 2018, exclusive of our federal research and development tax credit and California DTAs. However, it is possible that some of our foreign or domestic DTAs could ultimately expire unused, or future DTAs could be created, due to vesting or settlement of stock awards or other book to tax differences, in which we will not have sufficient taxable income in the future to fully utilize these and which will result in us recording a valuation allowance. Therefore, unless we are able to generate sufficient taxable income, a substantial valuation allowance to reduce our DTAs may be required, which would materially increase our tax expense in the period the valuation allowance is recorded and could have a material adverse impact on our financial condition and results of operations.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

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 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.

ITEM 3. LEGAL PROCEEDINGS.

For information with respect to Legal Proceedings, see Note “8. Commitments and Contingencies” to our consolidated financial statements in Part II, Item 8 of this Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock has been listed on the NYSE under the symbol "PEN" since September 18, 2015. Prior to that date, there was no established public trading market for our common stock. As of February 12, 2019, there were 45 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock with the total return for (i) the S&P Healthcare Equipment and (ii) the NYSE Composite for the period from September 18, 2015 (the date our common stock commenced trading on the NYSE) through December 31, 2018. Although our common stock was initially listed at $30.00 per share on the date our common stock was first listed on the NYSE, September 18, 2015, the $30.00 price is not reflected in the graph. Instead, the figures represented below assume an investment of $100 in our common stock at the closing price of $41.30 on September 18, 2015 and in the S&P Healthcare Equipment and NYSE Composite on September 18, 2015 and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

$100 investment in stock or index	Ticker	9/18/2015	12/31/2015	6/30/2016	12/30/2016	6/30/2017	12/29/2017	6/29/2018	12/31/2018
Penumbra	PEN	$ 100.00	$ 130.29	$ 144.07	$ 154.48	$ 212.47	$ 227.85	$ 334.50	$ 295.88
NYSE Composite	NYA	100.00	101.11	104.57	110.22	117.25	127.68	124.65	113.39
S&P 500 Healthcare Equipment Index	XHE	100.00	100.09	106.01	111.87	138.05	146.00	177.33	159.00

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds for use in the operation and expansion of our business, and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable

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laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The following selected consolidated financial data of Penumbra, Inc. should be read in conjunction with, and are qualified by reference to, the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes thereto included in this report. The consolidated statement of operations data for the years ended December 31, 2018, 2017 and 2016, and the consolidated balance sheet data as of December 31, 2018 and 2017, are derived from, and qualified by reference to, our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated statement of operations data for the year ended December 31, 2015 and 2014 and selected consolidated balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,				
	2018[1][2]	2017[3][4]	2016[5]	2015	2014
	(In thousands, except share and per share amounts)				
Consolidated Statement of Operations Data:					
Revenue	$444,938	$333,764	$263,317	$186,095	$125,510
Gross profit	292,533	217,142	170,829	124,058	82,842
Operating expenses:					
Acquired in-process research and development	30,835	—	—	—	—
Total operating expenses	293,385	215,977	172,179	119,879	79,833
(Loss) income from operations	(852)	1,165	(1,350)	4,179	3,009
Income (loss) before income taxes and equity in losses of unconsolidated investee	1,608	2,476	(869)	4,024	3,139
(Benefit from) provision for income taxes	(4,403)	(3,611)	(15,683)	1,659	894
Income before equity in losses of unconsolidated investee	6,011	6,087	14,814	2,365	2,245
Equity in losses of unconsolidated investee	(3,101)	(1,430)	—	—	—
Consolidated net income	$2,910	$4,657	$14,814	$2,365	$2,245
Net loss attributable to non-controlling interest	(3,691)	—	—	—	—
Net income (loss) attributable to Penumbra, Inc.	$6,601	$4,657	$14,814	$1,084	$(833)
Net income (loss) attributable to Penumbra, Inc. per share:					
Basic	$0.19	$0.14	$0.49	$0.09	$(0.18)
Diluted	$0.18	$0.13	$0.44	$0.08	$(0.18)
Weighted average shares used to compute net income (loss) per share attributable to common stockholders:					
Basic	34,138,176	32,978,065	30,464,583	11,993,429	4,609,375
Diluted	36,086,821	35,319,103	33,478,078	14,219,650	4,609,375

	Year Ended December 31,				
	2018[1][2]	2017[3][4]	2016[5]	2015	2014
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$67,850	$50,637	$13,236	$19,547	$3,290
Marketable investments	133,039	163,954	115,517	129,257	48,253
Total assets	515,006	476,667	308,254	263,848	121,381
Working capital	344,664	330,652	228,027	216,213	94,478
Convertible preferred stock	—	—	—	—	111,467
Total stockholders' equity (deficit)	422,415	400,408	266,547	232,522	(12,370)

(1) In the first quarter of 2018, the Company adopted Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), and its associated amendments. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. The Company applied the five step method outlined in the ASU to all revenue streams and elected to utilize the modified retrospective implementation method. As a result of adoption, the Company recorded a $0.3 million cumulative adjustment to its retained earnings at January 1, 2018. Refer to Note "2. Summary of Significant Accounting Policies" and Note "14. Revenues" for more information.
(2) During the year ended December 31, 2017, the Company formed MVI as a privately-held joint venture, with Sixense Enterprises, Inc. ("Sixense") for the purpose of exploring healthcare applications of virtual reality technology. On August 31, 2018, the Company acquired a controlling interest in MVI Health Inc. ("MVI") which was accounted for as an asset acquisition. In connection with the asset acquisition, the Company recorded a $30.8 million IPR&D charge in the

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consolidated statements of operations related to the acquired technology under development from MVI. Of the total IPR&D charge, $27.4 million was attributable to the net loss of Penumbra, Inc. Refer to Note “3. Investments and Fair Value of Financial Instruments” for more information.

(3) Income tax expense for the year ended December 31, 2017, includes $2.4 million of valuation allowance against the Company’s federal research and development tax credits and $15.4 million of deferred income tax due to the remeasurement of the Company’s DTAs at a 21% corporate income tax rate pursuant to the Tax Reform Act. Refer to our risk factor titled “Fluctuations in our effective tax rate and changes to tax laws may adversely affect us” in the section titled “Risk Factors-Risks Related to Our Finances and Capital Requirements.”

(4) In the third quarter of 2017, the Company acquired Crossmed S.p.A. (“Crossmed”). Crossmed is engaged in the business of distributing medical supplies and equipment in Italy, San Marino, Vatican City, and Switzerland. Refer to Note “5. Business Combination” for more information.

(5) In the fourth quarter of 2016, the Company elected to early adopt ASU 2016-09 which required excess tax benefit attributable to stock-based compensation to be recognized in the income statement. In connection with the adoption, the Company recorded a modified retrospective adjustment of $17.4 million in accumulated deficit.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this report entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by these forward-looking statements.

Overview

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 invested heavily in our product development capabilities in our major markets: neuro and vascular. 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 expect to continue to develop and build our portfolio of products, including our thrombectomy, embolization and access technologies. Generally, when we introduce a next generation product or a new product designed to replace a current product, sales of the earlier generation product or the product replaced decline. Our research and development activities are centered around the development of new products and clinical activities designed to support our regulatory submissions and demonstrate the effectiveness of our products. In addition to the development of thrombectomy, embolization and access technologies, in the second quarter of 2017, we formed MVI Health Inc. ("MVI"), a privately-held joint venture, with Sixense Enterprises, Inc. ("Sixense") for the purpose of exploring healthcare applications of virtual reality technology. At the time MVI was formed, we held 50% of the issued and outstanding equity of MVI with Sixense holding the remaining 50%. On August 31, 2018, we acquired a 90% controlling interest in MVI and expect to continue to make investments to further develop MVI's technology which is currently in the development stage.

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. In 2018, 34.7% of our revenue was generated from customers located outside of the United States. Our sales outside of the United States are denominated principally in the euro and Japanese yen, with some sales being denominated in other currencies. As a result, we have foreign exchange exposure, but do not currently engage in hedging.

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 annual increases of 33.3% and 26.8%, respectively.

Impact of the MVI Asset Acquisition

During the year ended December 31, 2018, we incurred a $30.8 million in-process research and development ("IPR&D") charge in connection with the acquisition of a controlling interest in MVI which was accounted for as an asset acquisition. As a result of the IPR&D charge, we generated an operating loss of $0.9 million for the year ended December 31, 2018. This compared to an operating income of $1.2 million and operating loss $1.4 million, respectively, for the years ended December 31, 2017 and 2016. Our results are discussed in more detail in the Results of Operations section below.

Factors Affecting Our Performance

There are a number of factors that have impacted, and we believe will continue to impact, our results of operations and growth. These factors include:

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The rate at which we grow our salesforce and the speed at which newly hired salespeople become fully effective can impact our revenue growth or our costs incurred in anticipation of such growth.

- Our industry is intensely competitive and, in particular, we compete with a number of large, well-capitalized companies. We must continue to successfully compete in light of our competitors' existing and future products and their resources to successfully market to the specialist physicians who use our products.

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- We must continue to successfully introduce new products that gain acceptance with specialist physicians and successfully transition from existing products to new products, ensuring adequate supply. In addition, as we introduce new products and expand our production capacity, we anticipate additional personnel will be hired and trained to build our inventory of components and finished goods in advance of sales, which may cause quarterly fluctuations in our operating results and financial condition.
- Publications of clinical results by us, our competitors and other third parties can have a significant influence on whether, and the degree to which, our products are used by specialist physicians and the procedures and treatments those physicians choose to administer for a given condition.
- The specialist physicians who use our products may not perform procedures during certain times of the year, such as those periods when they are at major medical conferences or are away from their practices for other reasons, the timing of which occurs irregularly during the year and from year to year.
- Most of our sales outside of the United States are denominated in the local currency of the country in which we sell our products. As a result, our revenue from international sales can be significantly impacted by fluctuations in foreign currency exchange rates.

In addition, we have experienced and expect to continue to experience meaningful variability in our quarterly revenue, gross profit and gross margin percentage as a result of a number of factors, including, but not limited to: the number of available selling days, which can be impacted by holidays; the mix of products sold; the geographic mix of where products are sold; the demand for our products and the products of our competitors; the timing of or failure to obtain regulatory approvals or clearances for products; increased competition; the timing of customer orders; inventory write-offs due to obsolescence; costs, benefits and timing of new product introductions; costs, benefits and timing of the acquisition and integration of businesses and product lines we may acquire; the availability and cost of components and raw materials; and fluctuations in foreign currency exchange rates. We may experience quarters in which we have significant revenue growth sequentially followed by quarters of moderate or no revenue growth. Additionally, we may experience quarters in which operating expenses, in particular research and development expenses, fluctuate depending on the stage and timing of product development.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the applicable periods. Management bases its estimates, assumptions and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. Historically, our critical accounting estimates have not differed materially from actual results. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition.

We believe the following critical accounting policies involve significant areas where management applies judgments and estimates in the preparation of our consolidated financial statements.

Revenue Recognition

Revenue is comprised of product revenue net of returns, discounts, administration fees and sales rebates. We adopted the guidance under Topic 606 of the Accounting Standards Codification (“ASC”) on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. Therefore, the comparative prior year information has not been adjusted and continues to be reported under ASC 605 with the impact of the adoption reflected in opening retained earnings. As a result of adoption, the cumulative impact to our retained earnings at January 1, 2018 was $0.3 million.

Under ASC 606, we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

Revenue from product sales is recognized either on the date of shipment or the date of receipt by the customer, but is deferred for certain transactions when control has not yet transferred. With respect to products that we consign to hospitals, which primarily consist of coils, we recognize revenue at the time hospitals utilize products in a procedure. The implementation of the new revenue standard did not have a material impact on the measurement or recognition of revenue from prior periods, however additional

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disclosures have been added in accordance with the guidance. Refer to Note "14. Revenues" to our consolidated financial statements in Part II, Item 8 of this Form 10-K for more information and disclosures on our revenue.

We defer revenue for amounts that we have already invoiced our customers for and are ultimately expected to be recognized as revenue, but for which not all revenue recognition criteria have been met.

Revenue is recorded at the net sales price, which includes estimates of variable consideration such as product returns utilizing historical return rates, rebates, discounts, and other adjustments to net revenue. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price. Variable consideration is included in revenue only to the extent that it is probable that a significant reversal of the revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. During the year ended December 31, 2018, we made no changes in estimates for variable consideration.

Our terms and conditions permit product returns and exchanges. We base our estimates for sales returns on actual historical returns over the prior three years and they are recorded as reductions in revenue at the time of sale. Upon recognition, we reduce revenue and cost of revenue for the estimated return. Return rates can fluctuate over time, but are sufficiently predictable to allow us to estimate expected future product returns.

Income Taxes

We account for income taxes using the asset and liability method, whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance to reduce the net deferred tax assets ("DTAs") to their estimated realizable value.

The calculation of our DTAs involves the use of estimates, assumptions and judgments while taking into account estimates of the amounts and type of future taxable income. DTAs are reduced to their estimated realizable value by a valuation allowance when it is more likely than not that the future realization of all or some of the DTAs will not be achieved. Valuation allowances related to DTAs can be affected by changes to tax laws, statutory tax rates, and projections of future taxable income.

The calculation of our current provision for income taxes involves the use of estimates, assumptions and judgments while taking into account current tax laws, interpretation of current tax laws and possible outcomes of future tax audits. We have established reserves to address potential exposures related to tax positions that could be challenged by tax authorities. Although we believe our estimates, assumptions and judgments to be reasonable, any changes in tax law or interpretation of tax law and the resolutions of potential tax audits could significantly impact the amounts provided for income taxes in our consolidated financial statements.

We follow FASB ASC 740-10 "Accounting for Uncertainty in Income Taxes" that prescribes a financial statement recognition threshold and measurement attribute for uncertain tax positions taken or expected to be taken on our income tax returns, and also provides guidance on derecognition, classification, interest and penalty accrual, accounting in interim periods, and disclosure requirements. We include interest and penalties related to unrecognized tax benefits within income tax expense in the accompanying consolidated statements of operations.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, ("the Tax Reform Act") was enacted. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, including but not limited to, lowering our U.S. corporate income tax rate from 34% to 21% effective January 1, 2018, implementing a territorial tax system, imposing a one-time transition tax on previously untaxed accumulated earnings and profits of foreign subsidiaries, and creating new taxes on foreign sourced earnings. Also on December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin 118 ("SAB 118") which provides guidance on accounting for tax effects of the Tax Reform Act. SAB 118 provides for a measurement period that should not extend beyond one year from the Tax Reform Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Reform Act for which the accounting under ASC 740 is complete.

As of December 31, 2018, we completed the accounting for tax effects of the Tax Reform Act under ASC 740 and therefore our financial statements reflect estimates of the tax affects based on current interpretations of the authoritative guidance available to date. In the reporting period ended December 31, 2017, we recorded an adjustment for the reduction of our U.S. corporate income tax rate to 21% effective January 1, 2018, resulting in a decrease to our DTAs in the amount of $15.4 million with a corresponding charge to income tax expense. No adjustments related to the federal tax rate reduction were made to our DTA balance subsequent to December 31, 2017. In the reporting period ended December 31, 2018, we completed the accounting for the one-time transition tax on the cumulative value of foreign earnings and profits that were previously not repatriated for U.S. income tax purposes, and completed our analysis of the new global intangible low-taxed income (“GILTI”)

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inclusion attributable to foreign sourced earnings. The tax effects of the one-time transition tax and GILTI income inclusion did not have a material impact on our financial statements as of and for the year ended December 31, 2018. We include U.S. taxes due on income inclusions attributable to GILTI as a period cost in the tax year incurred. Not all provisions of the Tax Reform Act are applicable to us in the tax year ended December 31, 2018. For example, we do not meet the statutory gross receipts threshold and therefore are not subject to the Base Erosion Anti-Abuse ("BEAT") minimum tax, and, due to current year losses we are not entitled to the Foreign-Derived Intangible Income ("FDII") deduction provisions.

The final impact of the Tax Reform Act may differ from our current estimates, due to, among other things, additional legislative guidance that may be issued which could change our current interpretation or application of the new tax law.

Significant domestic DTAs were generated in recent years, primarily due to excess tax benefits from stock option exercises and vesting of restricted stock. As of December 31, 2018, we had approximately $100.0 million, $88.7 million and $0.7 million of federal, state and foreign net operating loss carryforwards, respectively, available to offset future taxable income. The federal and state net operating loss carryforwards will begin to expire in 2036 and 2020, respectively. At December 31, 2018, we had research credits available to offset federal and state tax liabilities in the amount of $6.4 million and $8.0 million, respectively. The federal tax credits will begin to expire in 2024. California state tax credits have no expiration.

We assess the ability to realize the benefits of our DTAs in each reporting period by evaluating all available positive and negative evidence, objective and subjective in nature, including (1) cumulative results of operations in recent years, (2) sources of recent pre-tax income, (3) estimates of future taxable income, (4) the length of net operating loss ("NOL") carryforward periods, and (5) the ability to carry back losses to prior years. We also measure our current DTA balances against estimates of future income based on objectively verifiable operating results from the Company's recent history.

As of December 31, 2018, our net DTA balance was $30.9 million, after reduction of a valuation allowance of $17.3 million. We do not maintain valuation allowances against any of our foreign DTAs as we believe, at the required more-likely-than-not level of certainty, that our foreign subsidiaries will generate sufficient future taxable income to realize the benefit of their DTAs in full. In the period ended December 31, 2018, we measured our domestic net operating loss ("NOL") DTA balances against projections of future taxable income with consideration of relevant provisions of the Tax Reform Act, including but not limited to, the indefinite carryforward period for NOLs generated in years beginning on or after January 1, 2018. We also considered our three year cumulative income position, exclusive of the impact of excess tax deductions from stock-based compensation. We concluded that sufficient taxable income will be generated to realize the benefit of our domestic NOLs in full.

The Tax Reform Act extended the carryforward period of net operating losses generated in tax years beginning on or after January 1, 2018 such that the losses may be carried forward indefinitely, subject to an annual limitation of 80% of taxable income. The tax attribute ordering rules provide that to offset taxable income, net operating losses must be used in full prior to the utilization of tax credits. Accordingly, our federal research and development tax credit DTAs, which have a 20 year carryforward period, is expected to expire prior to utilization based on future projected taxable income.

After an evaluation of all available qualitative and quantitative evidence, both positive and negative in nature, we concluded that sufficient future taxable income will be generated to realize the benefits of our domestic DTAs prior to expiration, other than our federal research and development tax credit DTAs which are expected to expire before their utilization. As a result, in the period ended December 31, 2018, we continued to record a valuation allowance against our federal research and development tax credit. In addition, we continue to maintain a full valuation allowance against our California DTAs.

Our DTA balance also includes $3.0 million of tax attributes gained upon acquisition of a majority interest ownership in MVI. Refer to Note "3. Investments and Fair Value of Financial Instruments" for more information on the MVI Transfer Agreement. The acquired NOL DTAs are subject to Separate Return Limitation Year ("SRLY") rules which will limit the utilization of pre-acquisition tax attributes to offset future taxable income solely generated by MVI. As of December 31, 2018, we could not conclude, at the required more-likely-than-not level of certainty, that MVI will

generate sufficient taxable income to realize the benefit of its tax attributes prior to expiration and so a $3.0 million valuation allowance was recorded against the DTAs acquired from MVI.

We will continue to closely monitor the need for a valuation allowance against current and additional DTAs generated in each subsequent reporting period. The need for a valuation allowance can be impacted by actual operating results, forecasted financial performance, and variances between the two, and the rate at which future DTAs are generated. If our management was to determine that we would not be able to realize all or a portion of our net DTAs in the future, a valuation allowance related charge to earnings would be reflected in that period, which could have a material adverse impact on our financial condition and results of operations. If our management was to determine that we would be able to realize all net DTAs in the future, a

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reduction of the valuation allowance would be reflected as a benefit to earnings in that period, which could have a material positive impact on our financial condition and results of operations.

Goodwill

Goodwill represents the excess of the purchase price of an acquired business or assets over the fair value of the identifiable assets acquired and liabilities assumed. Goodwill is not amortized, but is tested for impairment at least annually, or more frequently if events or circumstances indicate the carrying value may no longer be recoverable and that an impairment loss may have occurred. Circumstances that could trigger an impairment test include, but are not limited to, a significant adverse change in the business climate or legal factors, an adverse action or assessment by a regulator, change in customers, target market and strategy, unanticipated competition, loss of key personnel, or change in reporting units. We operate as one segment, which is considered to be the sole reporting unit, and therefore goodwill is tested for impairment at the consolidated level.

The authoritative guidance allows an entity to assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If an entity determines that as a result of the qualitative assessment that it is more likely than not (i.e. greater than 50% likelihood) that the fair value of a reporting unit is less than its carrying amount, then the quantitative test is required. Otherwise, no further testing is required. The quantitative goodwill impairment test requires us to estimate and compare the fair value of our reporting unit with its carrying value.

Application of the goodwill impairment test requires judgments, including: identification of the reporting units, assigning goodwill to reporting units, a qualitative assessment to determine whether there are any impairment indicators, and determining the fair value of each reporting unit. Qualitative factors may include, but are not limited to, macroeconomic conditions, industry conditions, the competitive environment, changes in the market for our products and services, regulatory and political developments, cost factors, and entity specific factors such as strategies, overall financial performance (both current and projected) and market capitalization. In the fourth quarter of 2018 and 2017, we performed qualitative assessments for goodwill impairment and determined there we no indicators of impairment. Refer to Note “7. Goodwill” to our consolidated financial statements in Part II, Item 8 of this Form 10-K for more information.

Valuation of Intangible Assets

The valuation of identifiable intangible assets acquired in a business combination or asset acquisitions are determined based on detailed valuations that use information and assumptions provided by management. In determining the fair value of identifiable intangible assets, management provides its best estimates of inputs and assumptions that a market participant would use. Certain estimates used in this process include the amount and timing of projected milestone-based payments on sales that are considered probable and estimable, the amount and timing of projected future cash flows of each acquired intangible asset, the discount rate used to discount those cash flows to present value, the assessment of the asset’s life cycle, and the consideration of legal, technical, regulatory, economic, and competitive risks.

Indefinite-lived intangible assets are tested for impairment at least annually in the fourth quarter of each year, or more frequently if events or circumstances indicate that it is more likely than not that the asset is impaired. In conducting the annual impairment test for its indefinite-lived intangible assets, we may first perform a qualitative assessment to determine whether it is more likely than not (greater than 50% likelihood) that an indefinite-lived intangible asset is impaired. In accordance with the authoritative guidance, we may elect to bypass the qualitative assessment and proceed directly to the quantitative test to compare the fair value of the indefinite-lived intangible asset to the carrying amount. If we perform the quantitative test for indefinite-lived intangible assets, we generally use a discounted cash flow method based on the present value of projected cash flows to estimate fair value. Assumptions used in these cash flow projections are generally consistent with our internal forecasts and discounted using a rate that is reflective of the inherent risks and uncertainties associated with the projected cash flows of the business. Management believes the assumptions used for the impairment tests are consistent with those that would be utilized by a market participant performing similar analysis and valuations. Adverse changes in future market conditions or weaker operating results compared to our expectations may impact our projected cash flows, which could result in a potential impairment charge to the carrying value of our indefinite-lived intangible asset. In the fourth quarter of 2018, we performed a

quantitative impairment analysis on our indefinite-lived intangible asset and determined that the asset was not impaired. Refer to Note “6. Intangible Assets” to our consolidated financial statements in Part II, Item 8 of this Form 10-K for more information.

Finite-lived intangible assets are amortized over the estimated economic useful lives of the assets, which is the period during which expected cash flows support the fair value of such intangible assets. We review finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group’s carrying value. If an asset is considered impaired, the asset will be written down to the determined fair value based on discounted cash flows. We also periodically review the useful lives assigned to our

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intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the underlying intangible asset. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

Valuation of Contingent Consideration Liabilities

Certain agreements the Company enters into, including business combinations, involve the potential payment of future consideration that is contingent upon certain performance and revenue milestones being achieved. Contingent consideration is recorded at the acquisition date at fair value and is remeasured each reporting period using Level 3 inputs with the change in fair value recognized within sales, general and administrative expense in the consolidated statements of operations. The fair value of our contingent consideration is determined using a Monte-Carlo valuation model that simulates outcomes based on management estimates. Significant increases or decreases in the fair value of our contingent consideration liabilities can result from a number of factors, including changes in the timing and amount of projected revenue, our estimates of the likelihood of achieving certain milestones, as well as changes in discount periods and rates.

Components of Results of Operations

Revenue. We sell our products directly to hospitals and through distributors for use in procedures performed by specialist physicians to treat patients in two key markets: neuro and vascular disease. We sell our products through purchase orders, and we do not have long term purchase commitments from our customers. Revenue from product sales is recognized either on the date of shipment or the date of receipt by the customer, but is deferred for certain transactions when control has not yet transferred. With respect to products that we consign to hospitals, which primarily consist of coils, we recognize revenue at the time hospitals utilize products in a procedure. Revenue also includes shipping and handling costs that we charge to customers.

Cost of Revenue. Cost of revenue consists primarily of the cost of raw materials and components, personnel costs, including stock-based compensation, inbound freight charges, receiving costs, inspection and testing costs, warehousing costs, royalty expense, shipping and handling costs and other labor and overhead costs incurred in the manufacturing of products. We manufacture substantially all of our products in our manufacturing facility at our campus in Alameda, California.

Operating Expenses

Research and Development (“R&D”). R&D expenses primarily consist of product development, clinical and regulatory expenses, materials, depreciation and other costs associated with the development of our products. R&D expenses also include salaries, benefits and other related costs, including stock-based compensation, for personnel and consultants. We expense R&D costs as they are incurred.

Sales, General and Administrative (“SG&A”). SG&A expenses primarily consist of salaries, benefits and other related costs, including stock-based compensation, for personnel and consultants engaged in sales, marketing, finance, legal, compliance, administrative, facilities and information technology and human resource activities. Our SG&A expenses also include marketing trials, medical education, training, commissions, generally based on a percentage of sales, to direct sales representatives, amortization of acquired intangible assets and acquisition-related costs.

Income Tax Expense. We are taxed at the rates applicable within each jurisdiction in which we operate. The composite income tax rate, tax provisions, deferred tax assets and deferred tax liabilities will vary according to the jurisdiction in which profits arise. Tax laws are complex and subject to different interpretations by management and the respective governmental taxing authorities, and require us to exercise judgment in determining our income tax provision, our deferred tax assets and deferred tax liabilities and the potential valuation allowance recorded against our net DTAs. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not that the future realization of all or some of the DTAs will not be achieved.

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Results of Operations

The following table sets forth the components of our consolidated statements of operations in dollars and as a percentage of revenue for the periods presented:

	Year Ended December 31,					
	2018		2017		2016	
	(in thousands, except for percentages)					
Revenue	$444,938	100.0 %	$333,764	100.0 %	$263,317	100.0 %
Cost of revenue	152,405	34.3 %	116,622	34.9 %	92,488	35.1 %
Gross profit	292,533	65.7 %	217,142	65.1 %	170,829	64.9 %
Operating expenses:						
Research and development	36,165	8.1 %	31,661	9.5 %	23,875	9.1 %
Sales, general and administrative	226,385	50.9 %	184,316	55.2 %	148,304	56.3 %
Acquired in-process research and development	30,835	6.9 %	—	— %	—	— %
Total operating expenses	293,385	65.9 %	215,977	64.7 %	172,179	65.4 %
(Loss) income from operations	(852)	(0.2)%	1,165	0.3 %	(1,350)	(0.5)%
Interest income, net	2,964	0.7 %	2,653	0.8 %	2,323	0.9 %
Other expense, net	(504)	(0.1)%	(1,342)	(0.4)%	(1,842)	(0.7)%
Income (loss) before income taxes and equity in losses of unconsolidated investee	1,608	0.4 %	2,476	0.7 %	(869)	(0.3)%
(Benefit from) provision for income taxes	(4,403)	(1.0)%	(3,611)	(1.1)%	(15,683)	(6.0)%
Income before equity in losses of unconsolidated investee	6,011	1.4 %	6,087	1.8 %	14,814	5.6 %
Equity in losses of unconsolidated investee	(3,101)	(0.7)%	(1,430)	(0.4)%	—	— %
Consolidated net income	$2,910	0.7 %	$4,657	1.4 %	$14,814	5.6 %
Net loss attributable to non-controlling interest	(3,691)	(0.8)%	—	— %	—	— %
Net income attributable to Penumbra, Inc.	$6,601	1.5 %	$4,657	1.4 %	$14,814	5.6 %

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenue

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
Neuro	$294,333	$232,446	$61,887	26.6%
Vascular	150,605	101,318	49,287	48.6%
Total	$444,938	$333,764	$111,174	33.3%

Revenue increased $111.2 million, or 33.3%, to $444.9 million in 2018, from $333.8 million in 2017. Our revenue growth resulted from further market penetration of our existing products and sales of new products. Increased sales within our neuro and vascular businesses accounted for approximately 55% and 45% of the revenue increase, respectively, in the year ended December 31, 2018.

Revenue from our neuro products increased $61.9 million, or 26.6%, to $294.3 million in 2018, from $232.4 million in 2017. This was primarily attributable to increased sales of our Penumbra System and neuro access products, which accounted for approximately 85% and slightly less than 20% of the neuro revenue increase, respectively. Our neuro product sales experienced strong momentum due to further market penetration and growth in the market for endovascular treatment of stroke, which led to an increase in the number of procedures performed by specialist physicians using these products. This growth was partially offset by a decrease in sales of our neuro embolization products, which decreased by slightly less than 5% of the total change in neuro revenue, as demand for our neuro embolization products fluctuates from period to period due to the number of procedures performed. Prices for our neuro products remained substantially unchanged during the period.

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Revenue from our vascular products increased $49.3 million, or 48.6%, to $150.6 million in 2018, from $101.3 million in 2017. This was primarily attributable to increased sales of our Indigo System products, which accounted for slightly more than 45% of the vascular revenue increase for the year ended December 31, 2018. This increase was driven by further market penetration which led to increases in the number of procedures performed by specialist physicians using our products. Prices for our vascular products remained substantially unchanged during the period.

Revenue by Geographic Area

The following table presents revenue by geographic area and from countries that exceeded 10% of our total revenue, based on our customers' shipping destinations:

	Year Ended December 31,				Change	
	2018		2017		$	%
	(in thousands, except for percentages)					
United States	$290,716	65.3 %	$219,173	65.7 %	$71,543	32.6%
Japan	41,805	9.4 %	33,790	10.1 %	8,015	23.7%
Other International	112,417	25.3 %	80,801	24.2 %	31,616	39.1%
Total	$444,938	100.0%	$333,764	100.0%	$111,174	33.3%

Revenue from sales in international markets increased $39.6 million, or 34.6%, to $154.2 million in 2018, from $114.6 million in 2017. Revenue from international sales represented 34.7% and 34.3% of our total revenue in 2018 and 2017, respectively.

Gross Margin

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
Cost of revenue	$152,405	$116,622	$35,783	30.7%
Gross profit	$292,533	$217,142	$75,391	34.7%
Gross margin %	65.7 %	65.1 %		

Gross margin increased by 0.6 percentage points percentage points to 65.7% in 2018, from 65.1% in 2017. The increase in gross margin was primarily due to a more favorable product and geographic mix.

Research and Development ("R&D")

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
R&D	$36,165	$31,661	$4,504	14.2%
R&D as a percentage of revenue	8.1 %	9.5 %		

R&D expenses increased by $4.5 million or 14.2%, to $36.2 million in 2018, from $31.7 million in 2017. The increase was primarily due to a $4.3 million increase in personnel-related expenses primarily due to an increase in headcount to support our growth and a $3.2 million increase in product development and testing costs. This was partially offset by a $2.5 million decrease in clinical trial costs and a $0.8 million decrease in consultant and contractor expenses.

We have made investments, and plan to continue to make investments, in the development of our products, which includes hiring additional research and development employees. We expect our R&D expenditures in 2019 to significantly increase over 2018 levels due to the full year inclusion of R&D expenses from the acquisition of a controlling interest in MVI on August 31, 2018. In addition, we have experienced in the past, and may continue to experience in the future, variability in expenses incurred due to the timing and costs of clinical trials.

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Sales, General and Administrative ("SG&A")

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
SG&A	$226,385	$184,316	$42,069	22.8%
SG&A as a percentage of revenue	50.9 %	55.2 %		

SG&A expenses increased by $42.1 million, or 22.8%, to $226.4 million in 2018, from $184.3 million in 2017. The increase was primarily due to a $30.8 million increase in personnel-related expenses driven by an increase in headcount to support our growth, a $3.5 million increase in travel-related expenses, a $1.2 million increase related to a benefit recorded in the third quarter of the prior year due to a net refund of previously paid medical device excise tax, and a $1.0 million increase in information technology expenses.

As we continue to invest in our growth, we have expanded and expect to continue to expand our sales, marketing, general and administrative teams through the hiring of additional employees. In addition, we have experienced in the past, and may continue to experience in the future, variability in expenses incurred due to the timing and costs of investments in infrastructure to support the business. Further, while the medical device excise tax was suspended for an additional two-year period commencing January 1, 2018, absent further legislative action, it will be reinstated in 2020.

Acquired In-Process Research and Development

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
Acquired in-process research and development	$30,835	$ —	$30,835	not meaningful
Acquired in-process research and development as a percentage of revenue	6.9 %	—%		

During the year ended December 31, 2018, we recorded a $30.8 million acquired IPR&D charge in connection with the acquisition of a controlling interest in MVI which was accounted for as an asset acquisition.

Benefit from Income Taxes

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except for percentages)			
Benefit from income taxes	$(4,403)	$(3,611)	$(792)	21.9%
Effective tax rate	(273.8)%	(145.8)%		

Our benefit from income taxes increased $0.8 million, to a benefit of $4.4 million in 2018, from a benefit of $3.6 million in 2017. Our effective tax rate changed to (273.8)% in 2018, compared to (145.8)% in 2017. The tax benefit for the twelve months ended December 31, 2018 was primarily attributable to the inclusion of excess tax benefits from stock-based compensation associated with our US jurisdiction, offset by income taxes attributable to our foreign jurisdictions and a tax charge resulting from the IPR&D expense associated with the acquisition of a controlling interest in MVI, which is not deductible for tax purposes. The tax benefit for the twelve months ended December 31, 2017 was primarily attributable to excess tax benefits from stock-based compensation associated with our US jurisdiction, offset by income taxes attributable to our foreign jurisdictions, establishing a valuation allowance against our federal research and development tax credit deferred tax asset, and an adjustment to deferred income tax expense due to the reduced U.S. corporate income tax rate pursuant to the Tax Reform Act.

Our effective tax rate is driven by (1) permanent differences in taxable income for tax and financial reporting purposes, (2) tax expense attributable to our foreign jurisdictions, (3) changes to the valuation allowance maintained against our deferred tax assets, and (4) discrete tax adjustments such as excess tax benefits related to stock-based compensation. Our income tax provision is subject to volatility as the amount of excess tax benefits can fluctuate from period to period based on the price of our stock, the volume of share-based grants settled or vested, and the fair value

assigned to equity awards under U.S. GAAP. In

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addition, changes in tax law or our interpretation thereof, and changes to our valuation allowance could cause us to experience an effective tax rate significantly different from previous periods.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Revenue

	Year Ended December 31,		Change	
	2017	2016	$	%
	(in thousands, except for percentages)			
Neuro	$232,446	$185,533	$46,913	25.3%
Vascular	101,318	77,784	23,534	30.3%
Total	$333,764	$263,317	$70,447	26.8%

Revenue increased $70.4 million, or 26.8%, to $333.8 million in 2017, from $263.3 million in 2016. Our revenue growth resulted from further market penetration of our existing products and sales of new products or products with new indications. Increased sales within our neuro and vascular businesses accounted for approximately two-thirds and one-third of the revenue increase, respectively, in the year ended December 31, 2017.

Revenue from our neuro products increased $46.9 million, or 25.3%, to $232.4 million in 2017, from $185.5 million in 2016. This was primarily attributable to increased sales of our Penumbra System and neuro access products, which accounted for approximately 70% and 20% of the neuro revenue increase, respectively. Our neuro product sales experienced strong momentum due to further market penetration and growth in the market for endovascular treatment of stroke. The overall market growth has led to increases in the number of procedures performed by specialist physicians using our products. Further, there was a greater demand for our neuro access products due to the number of procedures performed. Prices for our neuro products remained substantially unchanged during the period.

Revenue from our vascular products increased $23.5 million, or 30.3%, to $101.3 million in 2017, from $77.8 million in 2016. This was primarily attributable to increased sales of our Indigo System products, which accounted for approximately half of the vascular revenue increase for the year ended December 31, 2017. This increase was driven by further market penetration which led to increases in the number of procedures performed by specialist physicians using our products. Prices for our vascular products remained substantially unchanged during the period.

Revenue by Geographic Area

The following table presents revenue by geographic area and from countries that exceeded 10% of our total revenue, based on our customers' shipping destinations:

	Year Ended December 31,				Change	
	2017		2016		$	%
	(in thousands, except for percentages)					
United States	$219,173	65.7%	$176,104	66.9%	$43,069	24.5%
Japan	33,790	10.1%	30,284	11.5%	3,506	11.6%
Other International	80,801	24.2%	56,929	21.6%	23,872	41.9%
Total	$333,764	100.0%	$263,317	100.0%	$70,447	26.8%

Revenue from sales in international markets increased $27.4 million, or 31.4%, to $114.6 million in 2017, from $87.2 million in 2016. Revenue from international sales represented 34.3% and 33.1% of our total revenue in 2017 and 2016, respectively.

Gross Margin

	Year Ended December 31,		Change	
	2017	2016	$	%
	(in thousands, except for percentages)			
Cost of revenue	$116,622	$92,488	$24,134	26.1%
Gross profit	$217,142	$170,829	$46,313	27.1%
Gross margin %	65.1%	64.9%		

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Gross margin remained relatively flat, increasing by 0.2 percentage points to 65.1% in 2017, from 64.9% in 2016.

Research and Development ("R&D")

	Year Ended December 31,		Change	
	2017	2016	$	%
	(in thousands, except for percentages)			
R&D	$31,661	$23,875	$7,786	32.6%
R&D as a percentage of revenue	9.5 %	9.1 %		

R&D expenses increased by $7.8 million, or 32.6%, to $31.7 million in 2017, from $23.9 million in 2016. The increase was primarily due to a $5.8 million increase in product development, testing and clinical trial costs and a $2.8 million increase in personnel-related expenses due to an increase in headcount. This was partially offset by a $0.7 million decrease in consultant, contractor and outside service costs.

Sales, General and Administrative ("SG&A")

	Year Ended December 31,		Change	
	2017	2016	$	%
	(in thousands, except for percentages)			
SG&A	$184,316	$148,304	$36,012	24.3%
SG&A as a percentage of revenue	55.2 %	56.3 %		

SG&A expenses increased by $36.0 million, or 24.3%, to $184.3 million in 2017, from $148.3 million in 2016. The increase was primarily due to a $31.3 million increase in personnel-related expenses largely attributable to an increase in headcount to support our growth and a $2.3 million increase related to marketing events. This was partially offset by a $1.2 million decrease related to a benefit from a net refund of previously paid medical device excise tax.

Benefit from Income Taxes

	Year Ended December 31,		Change	
	2017	2016	$	%
	(in thousands, except for percentages)			
Benefit from income taxes	$(3,611)	$(15,683)	$12,072	(77.0)%
Effective tax rate	(145.8)%	1,805.1 %		

Our benefit from income taxes decreased $12.1 million, to a benefit of $3.6 million in 2017, from a benefit of $15.7 million in 2016. Our effective tax rate changed to (145.8)% in 2017, compared to 1,805.1% in 2016. Our effective rate for 2017 and 2016 includes excess tax benefits attributable to stock-based compensation recognized in our income tax provision due to the retroactive adoption of ASU 2016-09 in the fourth quarter of 2016. The tax benefit for the twelve months ended December 31, 2017 was primarily attributable to excess tax benefits from stock-based compensation associated with our US jurisdiction, offset by income taxes attributable to our foreign jurisdictions, establishing a valuation allowance against our federal research and development tax credit deferred tax asset, and an adjustment to deferred income tax expense due to the reduced U.S. corporate income tax rate pursuant to the Tax Reform Act. The tax benefit for the twelve months ended December 31, 2016 was primarily attributable to excess tax benefits from stock-based compensation associated with our US jurisdiction, offset by income taxes attributable to our foreign jurisdictions.

Liquidity and Capital Resources

As of December 31, 2018, we had $344.7 million in working capital, which included $67.9 million in cash and cash equivalents and $133.0 million in marketable investments. As of December 31, 2018, we held approximately 34.5% of our cash and cash equivalents in foreign entities.

In March 2017, we issued and sold an aggregate of 1,495,000 shares of our common stock at public offering price of $76.00 per share, less the underwriters' discounts and commissions, pursuant to an underwritten public offering. We received approximately $106.3 million in net cash proceeds after deducting underwriting discounts and commissions of $6.8 million and other offering expenses of $0.5 million. We will continue to use the net proceeds from this

offering for general corporate purposes, including working capital, continued development of our products, including research and development and clinical trials, potential acquisitions and other business opportunities. Pending the use of the net proceeds from this offering, we are investing the net proceeds in investment grade, interest bearing securities.

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In addition to our existing cash and cash equivalents and marketable investment balances, our principal source of liquidity is our accounts receivable. We believe these sources of liquidity will be sufficient to meet our liquidity requirements for at least the next 12 months. Our principal liquidity requirements are to fund our operations, which includes, but is not limited to, maintaining sufficient levels of inventory to meet the anticipated demand of our customers, funding research and development activities and funding our capital expenditures. We may also lease or purchase additional facilities to facilitate our growth. We expect to continue to make investments as we launch new products, expand our manufacturing operations and further expand into international markets. We may, however, require or elect to secure additional financing as we continue to execute our business strategy. If we require or elect to raise additional funds, we may do so through equity or debt financing, which may not be available on favorable terms, could result in dilution to our stockholders and could require us to agree to covenants that limit our operating flexibility.

The following table summarizes our cash and cash equivalents, marketable investments and selected working capital data as of December 31, 2018 and December 31, 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	$67,850	$50,637
Marketable investments	133,039	163,954
Accounts receivable, net	81,896	58,007
Accounts payable	8,176	6,757
Accrued liabilities	57,886	44,825
Working capital[(1)]	344,664	330,652

(1) Working capital consists of total current assets less total current liabilities.

The following table sets forth, for the periods indicated, our beginning balance of cash and cash equivalents, net cash flows provided by (used in) operating, investing and financing activities and our ending balance of cash and cash equivalents:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Cash and cash equivalents at beginning of year	$50,637	$13,236	$19,547
Net cash provided by (used in) operating activities	28,808	12,691	(12,807)
Net cash (used in) provided by investing activities	(385)	(77,653)	687
Net cash (used in) provided by financing activities	(9,815)	104,359	7,126
Cash and cash equivalents at end of year	67,850	50,637	13,236

Net Cash Provided by (Used in) Operating Activities

Net cash provided by and used in operating activities consists primarily of net income adjusted for certain non-cash items (including depreciation and amortization, accretion of discounts or amortization of premium on marketable investments, stock-based compensation expense, loss on non-marketable equity investments, provision for doubtful accounts, inventory write-offs and write-downs, changes in deferred tax balances, changes in the fair value of contingent consideration and acquired IPR&D charges), and the effect of changes in working capital and other activities.

Net cash provided by operating activities was $28.8 million in 2018 and consisted of net income of $2.9 million and non-cash items of $56.2 million offset by net changes in operating assets and liabilities of $30.3 million. The change in operating assets and liabilities includes an increase in accounts receivable of $25.8 million, the increase in inventories of $22.3 million to support our revenue growth, partially offset by an increase in accrued expenses and other non-current liabilities of $14.2 million, a decrease in prepaid expenses and other current and non-current assets of $2.2 million, and an increase in accounts payable of $1.3 million as a result of the growth in our business activities.

Net cash provided by operating activities was $12.7 million in 2017 and consisted of net income of $4.7 million and non-cash items of $21.5 million offset by net changes in operating assets and liabilities of $13.5 million. The change in operating assets and liabilities includes the increase in inventories of $18.8 million to support our revenue growth, an increase in accounts

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receivable of $9.1 million, partially offset by an increase in accrued expenses and other non-current liabilities of $10.2 million, a decrease in prepaid expenses and other current and non-current assets of $2.4 million, and an increase in accounts payable of $1.9 million as a result of the growth in our business activities.

Net cash used in operating activities was $12.8 million in 2016 and consisted of net income of $14.8 million and non-cash items of $8.6 million offset by net changes in operating assets and liabilities of $36.2 million. The change in operating assets and liabilities includes the increase in inventories of $19.7 million to support our revenue growth, an increase in accounts receivable of $14.6 million, an increase in prepaid expenses and other current and non-current assets of $9.0 million, partially offset by an increase in accrued expenses and other non-current liabilities of $5.8 million and accounts payable of $1.4 million, as a result of the growth in our business activities.

Net Cash (Used in) Provided by Investing Activities

Net cash used in and provided by investing activities relates primarily to purchases of marketable investments, the acquisition of assets or a business, capital expenditures and non-marketable investments, partially offset by proceeds from maturities and sales of marketable investments.

Net cash used in investing activities was $0.4 million in 2018 and consisted of $20.4 million in payments, net of cash acquired, for the asset acquisition of MVI, capital expenditures of $9.6 million and contributions to non-marketable investments of $1.4 million. This was partially offset by proceeds from the maturities and sales of marketable investments, net of purchases, of $31.0 million.

Net cash used in investing activities was $77.7 million in 2017 and consisted of purchases of marketable investments, net of sales and maturities, of $48.1 million, capital expenditures of $12.5 million, $9.3 million related to the acquisition of Crossmed net of cash acquired, purchase of non-marketable investments of $5.3 million, and purchases of intangible of $2.5 million.

Net cash provided by investing activities was $0.7 million in 2016 and consisted of net proceeds from sales and maturities of marketable investments of $14.3 million, partially offset by capital expenditures of $13.6 million.

Net Cash Provided by Financing Activities

Net cash used in and provided by financing activities primarily relates to capital raising activities through equity and certain acquisition-related payments.

Net cash used in financing activities was $9.8 million in 2018 and primarily consisted of payments of employee taxes related to vested common and restricted stock of $17.7 million and payments related to the 2017 acquisition of Crossmed of $4.5 million, partially offset by proceeds from the issuance of stock under our employee stock purchase plan of $7.2 million and proceeds from exercises of stock options of $5.1 million.

Financing activities in 2017 provided net cash of $104.4 million due to proceeds from the issuance of common stock net of issuance costs of $106.3 million, proceeds from the issuance of stock under our employee stock purchase plan of $5.8 million and proceeds from exercises of stock options of $5.0 million. This was partially offset by payment of employee taxes related to vested common and restricted stock of $11.7 million and payment of debt obligations and credit facilities of $1.1 million.

Financing activities in 2016 provided net cash of $7.1 million due to proceeds from the issuance of stock under our employee stock purchase plan of $6.6 million, proceeds from exercises of stock options of $3.2 million, partially offset by payment of employee taxes related to vested common and restricted stock of $2.6 million.

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More than Five Years
	(in thousands)				
Rent obligations[1][2]	$68,370	$ 5,572	$ 11,263	$ 11,341	$ 40,194
Equipment lease obligations[3]	2,286	1,003	1,117	166	—
Purchase commitments[4]	23,084	15,689	7,395	—	—
Licensing arrangement obligations[5]	12,379	873	11,506	—	—
Acquisition-related obligations[6]	2,939	2,939	—	—	—
Total	$109,058	$ 26,076	$ 31,281	$ 11,507	$ 40,194

(1) Our rent obligations in the table above excludes potential obligations for additional space(s) that may be added to our lease by our landlord in the future. For example, if any space becomes vacant in any of the buildings located in the same business park as our corporate headquarters and manufacturing facilities in Alameda, California through 2025, that space will be added to the lease. The additional space could potentially result in approximately $1.6 million of annual rent expense based on current terms of the lease. The Company has a right of first offer to lease any space that becomes available after such date.

(2) Our rent obligations in the table above excludes our obligations related to a lease signed during the third quarter of 2018 in Roseville, California, due to uncertainty around the timing of when the lease will commence and payments will be due. The lease is expected to commence upon substantial completion of improvements to the building, which the Company anticipates will be completed within the next two years. The total amount of estimated minimum lease payments over the fifteen year lease term is approximately $40.9 million. Refer to Note “8. Commitments and Contingencies” for more information.

(3) We lease equipment and automobiles primarily under operating leases.

(4) Purchase commitments primarily consist of contracts with suppliers to purchase raw materials to be used to manufacture products.

(5) During the year ended December 31, 2017, we entered into an exclusive technology license agreement that requires us to make future revenue milestone-based payments on sales of products covered by the licensed intellectual property. While the agreement is cancelable, the future payments are estimable and probable as of December 31, 2018. Refer to Note “6. Intangible Assets” for more information.

(6) Acquisition-related obligations consist of purchase price obligations for the acquisition of Crossmed during the year ended December 31, 2017. The amount due in 1-3 years represents the fair value of contingent consideration related to future cash milestone payments as of December 31, 2018. Refer to Note “5. Business Combination” for more information.

At December 31, 2018, the liability recorded for uncertain tax positions, excluding associated interest and penalties, was approximately $1.6 million, which are not included in the table above. The ultimate amount and timing of any related future cash settlements cannot be predicted with reasonable certainty.

The amounts in the table above do not reflect royalty obligations under a license agreement as amounts due thereunder fluctuate depending on sales levels. Royalty expense included in cost of sales for the years ended December 31, 2018, 2017 and 2016 was $3.4 million, $4.1 million and $2.9 million, respectively. For more information on these royalty obligations, refer to Note “8. Commitments and Contingencies” to our consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We do not have any significant off-balance sheet arrangements or holdings in variable interest entities.

Recently Issued Accounting Standards

For information with respect to recently issued accounting standards and the impact of these standards on our consolidated financial statements, refer to Note “2. Summary of Significant Accounting Policies” to our consolidated

financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents and/or our marketable investments.

Interest Rate Risk. We had cash and cash equivalents of $67.9 million as of December 31, 2018, which consisted of funds held in general checking and savings accounts. In addition, we had marketable investments of $133.0 million, which consisted primarily of commercial paper, corporate bonds, U.S. agency and government sponsored securities, U.S. states and municipalities and U.S. Treasury. Our investment policy is focused on the preservation of capital and supporting our liquidity needs. Under the policy, we invest in highly rated securities, while limiting the amount of credit exposure to any one issuer other than the U.S. government. We do not invest in financial instruments for trading or speculative purposes, nor do we use leveraged financial instruments. We utilize external investment managers who adhere to the guidelines of our investment policy. A hypothetical 100 basis point change in interest rates would not have a material impact on the value of our cash and cash equivalents or marketable investments.

Foreign Exchange Risk Management. We operate in countries other than the United States, and, therefore, we are exposed to foreign currency risks. We bill most sales outside of the United States in local currencies, primarily euro and Japanese yen, with some sales being denominated in other currencies. We expect that the percentage of our sales denominated in foreign currencies may increase in the foreseeable future as we continue to expand into international markets. When sales or expenses are not denominated in U.S. dollars, a fluctuation in exchange rates could affect our net income. We do not believe our net income would be materially impacted by an immediate 10% adverse change in foreign exchange rates. We do not currently hedge our exposure to foreign currency exchange rate fluctuations; however, we may choose to hedge our exposure in the future.

We do not believe that inflation and changes in prices had a significant impact on our results of operations for any periods presented on our consolidated financial statements.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.
PENUMBRA, INC.
INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the stockholders and the Board of Directors of Penumbra, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Penumbra, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.
/s/ Deloitte & Touche LLP
San Francisco, California
February 26, 2019
We have served as the Company's auditor since 2008.

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Penumbra, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$67,850	$50,637
Marketable investments	133,039	163,954
Accounts receivable, net of doubtful accounts of $2,782 and $1,290 at December 31, 2018 and December 31, 2017, respectively	81,896	58,007
Inventories	115,741	94,901
Prepaid expenses and other current assets	12,200	14,735
Total current assets	410,726	382,234
Property and equipment, net	35,407	30,899
Intangible assets, net	27,245	23,778
Goodwill	7,813	8,178
Long-term investments (Note 3)	—	3,872
Deferred taxes	32,940	26,690
Other non-current assets	875	1,016
Total assets	$515,006	$476,667
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$8,176	$6,757
Accrued liabilities	57,886	44,825
Total current liabilities	66,062	51,582
Deferred rent	7,586	6,199
Other non-current liabilities	18,943	18,478
Total liabilities	92,591	76,259
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $.001 par value per share - 5,000,000 shares authorized, none issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $.001 par value per share - 300,000,000 shares authorized, 34,437,339 issued and outstanding at December 31, 2018; 300,000,000 shares authorized, 33,685,146 issued and outstanding at December 31, 2017	34	33
Additional paid-in capital	415,084	396,810
Accumulated other comprehensive (loss) income	(1,942)	1,569
Retained earnings	9,064	1,996
Total Penumbra, Inc. stockholders' equity	422,240	400,408
Non-controlling interest	175	—
Total stockholders' equity	$422,415	$400,408
Total liabilities and stockholders' equity	$515,006	$476,667

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

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Penumbra, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenue	$444,938	$333,764	$263,317
Cost of revenue	152,405	116,622	92,488
Gross profit	292,533	217,142	170,829
Operating expenses:			
Research and development	36,165	31,661	23,875
Sales, general and administrative	226,385	184,316	148,304
Acquired in-process research and development	30,835	—	—
Total operating expenses	293,385	215,977	172,179
(Loss) income from operations	(852)	1,165	(1,350)
Interest income, net	2,964	2,653	2,323
Other expense, net	(504)	(1,342)	(1,842)
Income (loss) before income taxes and equity in losses of unconsolidated investee	1,608	2,476	(869)
Benefit from income taxes	(4,403)	(3,611)	(15,683)
Income before equity in losses of unconsolidated investee	6,011	6,087	14,814
Equity in losses of unconsolidated investee	(3,101)	(1,430)	—
Consolidated net income	$2,910	$4,657	$14,814
Net loss attributable to non-controlling interest	(3,691)	—	—
Net income attributable to Penumbra, Inc.	$6,601	$4,657	$14,814
Net income attributable to Penumbra, Inc. per share:			
Basic	$0.19	$0.14	$0.49
Diluted	$0.18	$0.13	$0.44
Weighted average shares outstanding:			
Basic	34,138,176	32,978,065	30,464,583
Diluted	36,086,821	35,319,103	33,478,078

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

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Penumbra, Inc.
Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Consolidated net income	$2,910	$4,657	$14,814
Other comprehensive income, net of tax:			
Foreign currency translation adjustments, net of tax	(3,246)	6,387	(2,631)
Net change in unrealized (losses) gains on available-for-sale securities, net of tax	(265)	(130)	58
Total other comprehensive (loss) income, net of tax	$(3,511)	$6,257	$(2,573)
Consolidated comprehensive (loss) income	$(601)	$10,914	$12,241
Net loss attributable to non-controlling interest	$(3,691)	$—	$—
Comprehensive income attributable to Penumbra, Inc.	$3,090	$10,914	$12,241

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

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Penumbra, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Accumulated Other Comprehensive (Loss) Income	Retained Earnings (Accumulated Deficit)	Total Penumbra, Inc. Stockholders' Equity	Non-Controlling Interest	Total Stockholders' Equity
	Shares	Amount							
Balance at December 31, 2015	29,897,860	$ 30	$252,087	$ (5)	$ (2,115)	$ (17,475)	$232,522	$ —	$232,522
Issuance of common stock	1,043,223	1	3,167	—	—	—	3,168	—	3,168
Issuance of common stock under employee stock purchase plan	214,025	—	6,578	—	—	—	6,578	—	6,578
Shares held for tax withholdings	(46,280)	—	(2,624)	—	—	—	(2,624)	—	(2,624)
Stock-based compensation	—	—	14,657	—	—	—	14,657	—	14,657
Note received from a stockholder	—	—	—	5	—	—	5	—	5
Other comprehensive loss	—	—	—	—	(2,573)	—	(2,573)	—	(2,573)
Net income	—	—	—	—	—	14,814	14,814	—	14,814
Balance at December 31, 2016	31,108,828	31	273,865	—	(4,688)	(2,661)	266,547	—	266,547
Issuance of common stock	1,131,344	—	5,048	—	—	—	5,048	—	5,048
Issuance of common stock under employee stock purchase plan	91,685	—	5,809	—	—	—	5,809	—	5,809
Issuance of common stock upon underwritten public offering, net of issuance cost	1,495,000	2	106,267	—	—	—	106,269	—	106,269
Shares held for tax withholdings	(141,711)	—	(11,686)	—	—	—	(11,686)	—	(11,686)
Stock-based compensation	—	—	17,507	—	—	—	17,507	—	17,507
Other comprehensive income	—	—	—	—	6,257	—	6,257	—	6,257
Net income	—	—	—	—	—	4,657	4,657	—	4,657
Balance at December 31, 2017	33,685,146	33	396,810	—	1,569	1,996	400,408	—	400,408
	774,475	1	5,063	—	—	—	5,064	—	5,064

Issuance of common stock									
Issuance of common stock under employee stock purchase plan	74,344	—	7,231	—	—	—	7,231	—	7,231
Issuance of common stock pursuant to royalty buyout	53,256	—	5,256	—	—	—	5,256	—	5,256
Shares held for tax withholdings	(149,882)	—	(17,725)	—	—	—	(17,725)	—	(17,725)
Stock-based compensation	—	—	18,449	—	—	—	18,449	—	18,449
Cumulative effect adjustments[1]	—	—	—	—	—	467	467	—	467
Asset acquisition date fair value of non-controlling interest	—	—	—	—	—	—	—	3,366	3,366
Capital contribution from non-controlling interest	—	—	—	—	—	—	—	500	500
Other comprehensive income	—	—	—	—	(3,511)	—	(3,511)	—	(3,511)
Net income (loss)	—	—	—	—	—	6,601	6,601	(3,691)	2,910
Balance at December 31, 2018	34,437,339	$ 34	$415,084	$ —	$ (1,942)	$ 9,064	$422,240	$ 175	$422,415

(1) Cumulative effect adjustments relate to the adoption of Accounting Standard Update ("ASU") No. 2014-09 - Revenue from Contracts with Customers ("Topic 606"), ASU No. 2016-16 - Income Taxes ("Topic 740"), and ASU No. 2018-02 - Income Statement - Reporting Comprehensive Income ("Topic 220"). Refer to the accompanying notes, including Note "2. Summary of Significant Accounting Policies," for more information.

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

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Penumbra, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$2,910	$4,657	$14,814
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	6,168	3,781	2,297
(Accretion of discount) amortization of premium on marketable investments	(161)	591	997
Stock-based compensation	18,422	17,812	14,637
Loss on non-marketable equity investments	3,101	1,430	—
Provision for doubtful accounts	1,563	606	216
Inventory write-offs and write-downs	1,700	1,037	2,667
Deferred taxes	(6,480)	(4,288)	(12,378)
Acquired in-process research and development	30,835	—	—
Change in fair value of contingent consideration	950	109	—
Other	60	445	135
Changes in operating assets and liabilities:			
Accounts receivable	(25,762)	(9,118)	(14,560)
Inventories	(22,288)	(18,826)	(19,737)
Prepaid expenses and other current and non-current assets	2,231	2,436	(9,043)
Accounts payable	1,329	1,851	1,375
Accrued expenses and other non-current liabilities	14,230	10,168	5,773
Net cash provided by (used in) operating activities	28,808	12,691	(12,807)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Asset acquisition (Note 3) and acquisition of business (Note 5), net of cash acquired	(20,414)	(9,253)	—
Contributions to non-marketable investments	(1,382)	(5,265)	—
Purchases of marketable investments	(108,227)	(189,658)	(63,346)
Proceeds from sales of marketable investments	12,129	28,752	12,997
Proceeds from maturities of marketable investments	127,112	112,803	64,671
Acquisition of intangible assets from a licensing agreement	—	(2,500)	—
Purchases of property and equipment	(9,603)	(12,532)	(13,635)
Net cash (used in) provided by investing activities	(385)	(77,653)	687
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock upon underwritten public offering, net of issuance cost	—	106,267	—
Proceeds from exercises of stock options	5,064	5,048	3,172
Proceeds from issuance of stock under employee stock purchase plan	7,231	5,809	6,578
Payment of obligations on debt and credit facilities	(404)	(1,079)	—
Payment of employee taxes related to vested common and restricted stock	(17,725)	(11,686)	(2,624)
Payment of acquisition-related obligations	(4,481)	—	—
Proceeds from capital contribution from non-controlling interest	500	—	—
Net cash (used in) provided by financing activities	(9,815)	104,359	7,126
Effect of foreign exchange rate changes on cash and cash equivalents	(1,395)	(1,996)	(1,317)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	17,213	37,401	(6,311)
CASH AND CASH EQUIVALENTS—Beginning of period	50,637	13,236	19,547
CASH AND CASH EQUIVALENTS—End of period	$67,850	$50,637	$13,236

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for income taxes	$156	$141	$2,149
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common shares issued as consideration in connection with a buyout agreement (Notes 6, 8 and 9)	$5,256	$—	$—
Purchase of property and equipment funded through accounts payable and accrued liabilities	$1,037	$977	$1,442
Asset acquisition (Note 3) and acquisition of business (Note 5) related contingent and working capital liabilities	$4,000	$6,067	$—
Licensing agreement related contingent liabilities	$—	$12,717	$—

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

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Penumbra, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of Business

Penumbra, Inc. (the "Company") is a global healthcare company focused on innovative therapies. The Company designs, develops, manufactures and markets medical devices and has a broad portfolio of products that addresses challenging medical conditions and significant clinical needs.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Certain changes in presentation were made in the consolidated financial statements for the year ended December 31, 2017 and 2016, to conform to the presentation for the year ended December 31, 2018.

The consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries and its majority-owned subsidiary, MVI Health Inc. ("MVI"). On August 31, 2018, the Company acquired a controlling interest in MVI. The portion of equity not attributable to the Company is considered non-controlling interest and was recorded at fair value as of the acquisition date. The amounts attributable to non-controlling interest are classified separately in the consolidated financial statements. Any subsequent changes in the Company's ownership interest while the Company retains its controlling interest in MVI will be accounted for as equity transactions. Refer to Note "3. Investments and Fair Value of Financial Instruments" for more information on the asset acquisition of MVI. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and equity accounts; disclosure of contingent assets and liabilities at the date of the financial statements; and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to marketable investments, provisions for doubtful accounts, the amount of variable consideration included in the transaction price, warranty reserve, valuation of inventories, useful lives of property and equipment, income taxes, contingent consideration and other contingencies, among others. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other data. Actual results could differ from those estimates.

Segments

The Company determined its operating segment on the same basis that it uses to evaluate its performance internally. The Company has one business activity: the design, development, manufacturing and marketing of innovative medical devices, and operates as one operating segment. The Company's chief operating decision-maker ("CODM"), its Chief Executive Officer, reviews its consolidated operating results for the purpose of allocating resources and evaluating financial performance. The Company's entity-wide disclosures are included in Note "14. Revenues."

Foreign Currency Translation

The Company's consolidated financial statements are prepared in United States Dollars ("USD"). Its foreign subsidiaries use their local currency as their functional currency and maintain their records in the local currency. Accordingly, the assets and liabilities of these subsidiaries are translated into USD using the current exchange rates in effect at the balance sheet date and equity accounts are translated into USD using historical rates. Revenues and expenses are translated using the average exchange rates in effect for the year involved. The resulting foreign currency translation adjustments are recorded in accumulated other comprehensive income (loss) in the consolidated balance sheets. Transactions denominated in currencies other than the respective functional currencies are translated at exchange rates as of the date of transaction with foreign currency gains and losses recorded in other expense, net in the consolidated

statements of operations. The Company realized net foreign currency transaction losses of $0.9 million, $1.0 million and $0.7 million during the years ended December 31, 2018, 2017 and 2016, respectively.

As the Company’s international operations grow, its risks associated with fluctuation in currency rates will become greater, and the Company will continue to reassess its approach to managing this risk. In addition, currency fluctuations or a weakening

USD can increase the costs of the Company's international expansion. To date, the Company has not entered into any foreign currency hedging contracts.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, marketable investments (as described in greater detail in this footnote under the header "Cash, Cash Equivalents and Marketable Investments" below) and accounts receivable. The majority of the Company's cash is held by one financial institution in the U. S. in excess of federally insured limits. The Company maintained investments in money market funds that were not federally insured during the year ended December 31, 2018 and held cash in foreign entities of approximately $23.4 million and $15.0 million at December 31, 2018 and 2017, respectively, which was not federally insured.

The Company's revenue has been derived from sales of its products in the United States and international markets. The Company uses both its own salesforce and independent distributors to sell its products. Concentrations of credit risk with respect to accounts receivable are limited due to the large number of entities comprising the Company's customer base. The Company performs ongoing credit evaluations of its customers, including its distributors, does not require collateral, and maintains allowances for potential credit losses on customer accounts when deemed necessary.

During the year ended December 31, 2018, no customer accounted for greater than 10% of the Company's revenue. During December 31, 2017 and 2016, one customer, a distributor, accounted for 10.1% and 11.5%, respectively, of the Company's revenue. No customer accounted for greater than 10% of the Company's accounts receivable balance as of December 31, 2018 or 2017.

Significant Risks and Uncertainties

The Company is subject to risks common to medical device companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, uncertainty of market acceptance of products and the potential need to obtain additional financing. The Company is dependent on third party suppliers, in some cases single-source suppliers. There can be no assurance that the Company's products will continue to be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all.

The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company sells its products. If the Company is denied such approvals or clearances or such approvals or clearances are delayed, it may have a material adverse impact on the Company's results of operations, financial position and liquidity.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities.

Cash, Cash Equivalents and Marketable Investments

The Company invests its cash primarily in highly liquid corporate debt securities, debt instruments of U.S. federal and municipal governments, and their agencies, and in money market funds. All highly liquid investments with stated maturities of three months or less from the date of purchase are classified as cash equivalents; all highly liquid investments with stated maturities of greater than three months are classified as marketable investments. The majority of the Company's cash and investments are held in U.S. banks.

The Company determines the appropriate classification of its investments in marketable investments at the time of purchase and re-evaluates such designation at each balance sheet date. The Company's marketable investments have been classified and accounted for as available-for-sale. Investments with remaining maturities of more than one year are viewed by the Company as available to support current operations and are classified as current assets under the caption marketable investments in the accompanying consolidated balance sheets. Investments in marketable

investments are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized

gains or losses on the sale of marketable investments are determined on a specific identification method, and such gains and losses are reflected as a component of other income (expense), net.

Impairment of Marketable Investments

After determining the fair value of available-for-sale debt instruments, unrealized gains or losses on these securities are recorded to accumulated other comprehensive income (loss) until either the security is sold or the Company determines that the decline in value is other-than-temporary. The primary differentiating factors that the Company considers in classifying impairments as either temporary or other-than-temporary impairments is the intent and ability to retain the investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value, the length of the time and the extent to which the market value of the investment has been less than cost, the financial condition, and near-term prospects of the issuer. There were no other-than-temporary impairments for the years ended December 31, 2018, 2017 or 2016.

Non-Marketable Equity Investments

Entities in which the Company has at least a 20%, but not more than a 50%, interest are accounted for under the equity method unless it is determined that the Company has a controlling financial interest in the entity, in which case the entity would be consolidated. Non-marketable equity investments are classified as long-term investments on the consolidated balance sheet. The Company's proportionate share of the operating results of its non-marketable equity method investments are recorded as profit or loss and presented in equity in losses of unconsolidated investee, in the consolidated statements of operations. See Note "3. Investments and Fair Value of Financial Instruments" for further details.

Accounts Receivable

Accounts receivable are stated at invoice value less estimated allowances for doubtful accounts. The Company continually monitors customer payments and maintains a reserve for estimated losses resulting from its customers' inability to make required payments. The Company considers factors such as historical experience, credit quality, age of the accounts receivable balances, geographic related risks and economic conditions that may affect a customer's ability to pay. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, a specific allowance is recorded against amounts due, and thereby reduces the net recognized receivable to the amount reasonably believed to be collectible.

Inventories

Inventories are stated at the lower of cost (determined under the first-in first-out method) or net realizable value. Write-downs are provided for raw materials, components or finished goods that are determined to be excessive or obsolete. The Company regularly reviews inventory quantities in consideration of actual loss experience, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. As a result of these evaluations, the Company recognized total write-offs and write-downs of $1.7 million, $1.0 million, and $2.7 million for the years ended December 31, 2018, 2017 and 2016.

Property and Equipment, net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life. Machinery and equipment and furniture and fixtures are depreciated over a five to ten year period and computers and software are depreciated over two to five years. Upon retirement or sale, the cost and the related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to consolidated statements of operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based

either on discounted cash flows or appraised value, depending on the nature of the asset. There was no impairment of long-lived assets during the years ended December 31, 2018, 2017 or 2016.

Contingent Consideration

Certain agreements the Company enters into, including business combinations, involve the potential payment of future consideration that is contingent upon certain performance and revenue milestones being achieved. A contingent consideration

liability is recorded at the acquisition date at fair value and is remeasured each reporting period with the change in fair value recognized generally within sales, general and administrative expense, depending on the nature of the contingent consideration liability, in the consolidated statements of operations.

As of December 31, 2018 and 2017, the Company's contingent consideration relates to milestone payments for the acquisition of Crossmed S.p.A. ("Crossmed"). For more information with respect to the fair value of contingent consideration, refer to Note "5. Business Combination."

Intangible Assets

Intangible assets primarily consist of purchased rights to licensed technology, customer relationships, and trade secrets and processes.

Indefinite-lived intangible assets relate to an exclusive right to licensed technology. The acquired licensed technology is accounted for as an indefinite-lived intangible asset. Upon the commercialization of the underlying product utilizing the licensed technology, the capitalized amount will be amortized over its estimated useful life. Indefinite-lived intangible assets are tested for impairment at least annually, in the fourth quarter, or more frequently if events or circumstances indicate that it is more likely than not that the asset is impaired. If the fair value of the asset is less than the carrying amount, an impairment loss would be recognized in an amount equal to the difference between the carrying amount and the fair value. Refer to Note "6. Intangible Assets" for more information on the Company's intangible assets.

Finite-lived intangible assets are amortized over the estimated economic useful lives of the assets, which is the period during which expected cash flows support the fair value of such intangible assets. The Company reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. Refer to Note "6. Intangible Assets" for more information on the Company's intangible assets.

Goodwill

Goodwill represents the excess of the purchase price of an acquired business or assets over the fair value of the identifiable assets acquired and liabilities assumed. Goodwill is not amortized, but is tested for impairment annually in the fourth quarter, or more frequently if events or circumstances indicate the carrying value may no longer be recoverable and that an impairment loss may have occurred. The Company operates as one segment, which is considered to be the sole reporting unit, and therefore goodwill is tested for impairment at the consolidated level. Refer to Note "5. Business Combination" and Note "7. Goodwill" for more information.

Revenue Recognition

Revenue is comprised of product revenue net of returns, discounts, administration fees and sales rebates. The Company adopted the guidance under ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. Therefore, the comparative prior year information has not been adjusted and continues to be reported under ASC 605 with the impact of the adoption reflected in opening retained earnings in 2018. Under ASC 606, the Company recognizes revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Revenue from product sales is recognized either on the date of shipment or the date of receipt by the customer, but is deferred for certain transactions when control has not yet transferred. With respect to products that the Company consigns to hospitals, which primarily consist of coils, the Company recognizes revenue at the time hospitals utilize products in a procedure.

Deferred revenue represents amounts that the Company has already invoiced its customers and that are ultimately expected to be recognized as revenue, but for which not all revenue recognition criteria have been met. As of December 31, 2018 and December 31, 2017, respectively, the Company's deferred revenue balance was not material.

Revenue is recorded at the net sales price, which includes estimates of variable consideration such as product returns utilizing historical return rates, rebates, discounts, and other adjustments to net revenue. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be

included in the transaction price. Variable consideration is included in revenue only to the extent that it is probable that a significant reversal of the revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company’s terms and conditions permit product returns and exchanges. The Company bases its estimates for sales returns on actual historical returns over the prior three years and they are recorded as reductions in revenue at the time of sale.

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Notes to Consolidated Financial Statements (Continued)

Upon recognition, the Company reduces revenue and cost of revenue for the estimated return. Return rates can fluctuate over time, but are sufficiently predictable to allow the Company to estimate expected future product returns. For more information and disclosures on the Company's revenue, refer to Note "14. Revenues."

Shipping Costs

Shipping and handling costs charged to customers are recorded as revenue. Shipping and handling costs are included in cost of revenue.

Research and Development ("R&D") Costs

R&D costs primarily consist of product development, clinical and regulatory expenses, materials, depreciation and other costs associated with the development of the Company's products. R&D costs also include related personnel and consultants' salaries, benefits and related costs, including stock-based compensation. The Company expenses R&D costs as they are incurred.

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites. The Company estimates preclinical and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Advertising Costs

Advertising costs are included in sales, general and administrative expenses and are expensed as incurred. Advertising costs were $0.5 million, $0.7 million and $0.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Stock-Based Compensation

The Company recognizes the cost of stock-based compensation in the financial statements based upon fair value. The fair value of restricted stock and restricted stock unit ("RSU") awards is determined based on the number of units granted and the closing price of the Company's common stock as of the grant date. The fair value of each purchase under the employee stock purchase plan ("ESPP") is estimated at the beginning of the offering period using the Black-Scholes option pricing model. The fair value of stock options is determined as of the grant date using the Black-Scholes option pricing model. The Company's determination of the fair value of equity-settled awards is impacted by the price of the Company's common stock as well as changes in assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the expected term that awards will remain outstanding, expected common stock price volatility over the term of the awards, risk-free interest rates and expected dividends.

The fair value of an award is recognized over the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense recognized at fair value includes the impact of estimated forfeitures. The Company estimates future forfeitures at the date of grant and revises the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. To the extent actual forfeiture results differ from the estimates, the difference is recorded as a cumulative adjustment in the period forfeiture estimates are revised. No compensation cost is recorded for awards that do not vest.

Prior to the adoption of Accounting Standard Update ("ASU") No. 2018-07, "Compensation – Stock Compensation," the Company recorded its equity instruments issued to non-employees at their fair value on the measurement date and were subject to periodic adjustments as the Company remeasured the fair value of the non-employee awards at each reporting period prior to vesting and at the vesting dates of each non-employee award. In the third quarter of 2018, the Company adopted ASU 2018-07 and recognizes the fair value of non-employee awards over the requisite service period (usually the vesting period) on a straight-line basis. Therefore, equity instruments issued to non-employees are recorded at their fair value on the grant date in the same manner as employee awards. The fair value of these equity

instruments is expensed over the service period.

Estimates of the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, are affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value of the award and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. For all stock options granted prior to

the Company's IPO, the Company estimated the volatility data based on a study of publicly traded industry peer companies. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award. For all stock options granted to date, the Company used the Staff Accounting Bulletin, No. 110 ("SAB 110") simplified method to calculate the expected term, which is the average of the contractual term and vesting period.

Income Taxes

The Company accounts for income taxes using the asset and liability method, whereby deferred tax asset ("DTA") and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance to reduce the net DTAs to their estimated realizable value.

The calculation of the Company's current provision for income taxes involves the use of estimates, assumptions and judgments while taking into account current tax laws, interpretation of current tax laws and possible outcomes of future tax audits. The Company has established reserves to address potential exposures related to tax positions that could be challenged by tax authorities. Although the Company believes its estimates, assumptions and judgments to be reasonable, any changes in tax law or its interpretation of tax laws and the resolutions of potential tax audits could significantly impact the amounts provided for income taxes in the Company's consolidated financial statements.

The calculation of the Company's DTA balance involves the use of estimates, assumptions and judgments while taking into account estimates of the amounts and type of future taxable income. Actual future operating results and the underlying amount and type of income could differ materially from the Company's estimates, assumptions and judgments thereby impacting the Company's financial position and results of operations.

The Company follows the guidance relating to accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

The Company includes interest and penalties related to unrecognized tax benefits within income tax expense in the accompanying consolidated statements of operations.

Comprehensive Income

Comprehensive income consists of net income, unrealized gains or losses on available-for-sale investments and the effects of foreign currency translation adjustments. The Company presents comprehensive income and its components in the consolidated statements of comprehensive (loss) income.

Net Income (Loss) Per Share of Common Stock

The Company's basic net income (loss) attributable to Penumbra, Inc. per share is calculated by dividing the net income attributable to Penumbra, Inc. per share by the weighted average number of shares of common stock outstanding for the period. The diluted net income (loss) per share attributable to Penumbra, Inc. is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, options to purchase common stock, restricted stock and restricted stock units are considered common stock equivalents.

Recent Accounting Guidance

Recently Adopted Accounting Standards

In the first quarter of 2018, the Company adopted ASU No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), and its associated amendments. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company applied the five step method outlined in the ASU to all revenue streams and elected to utilize the modified retrospective implementation method. The

additional disclosures required by the ASU have been included in Note “14. Revenues.”

In the first quarter of 2018, the Company adopted ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, a consensus of the Financial Accounting Standards Board (“FASB”) Emerging Issues Task Force. Under the standard, restricted

cash and restricted cash equivalent amounts are presented within cash and cash equivalents when reconciling the total beginning and ending amounts shown on the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet is required. The adoption of this standard did not have a material impact to the statement of cash flow for the years ended December 31, 2018, 2017 and 2016, as the Company did not hold any restricted cash as of December 31, 2018, 2017 and 2016.

In the first quarter of 2018, the Company adopted ASU No. 2017-09, Compensation - Stock Compensation - Scope of Modification Accounting. The standard provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The standard is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The guidance was adopted on a prospective basis in the first quarter of 2018 and did not have any impact upon adoption.

In the first quarter of 2018, the Company adopted ASU No. 2018-02, Income Statement - Reporting Comprehensive Income. The standard allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act of 2017 (the “Tax Reform Act”). The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for any interim and annual financial statements that have not yet been issued. The Company elected to early adopt this standard on a prospective basis in the first quarter of 2018 and reclassify the stranded tax effects resulting from the Tax Reform Act from accumulated other comprehensive income to retained earnings. There were no additional income tax effects resulting from the Tax Reform Act reclassified from accumulated comprehensive income to retained earnings. The adoption of this standard did not have a material impact on the Company’s financial position.

In the first quarter of 2018, the Company adopted ASU No. 2018-05, Income Taxes (“Topic 740”): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, which included amendments to expand income tax accounting and disclosure guidance pursuant to SEC Staff Accounting Bulletin No. 118 (“SAB 118”) issued by the SEC in December 2017. SAB 118 provides guidance on accounting for the income tax effects of the Tax Reform Act. Refer to Note “12. Income Taxes” for more information and disclosures related to this amended guidance.

In the third quarter of 2018, the Company adopted ASU No. 2018-07, Compensation – Stock Compensation (“Topic 718”): Improvements to Nonemployee Share-Based Payment Accounting, which simplifies the accounting and reporting for share-based payments granted to nonemployees for goods and services. Under the new guidance, payments to nonemployees would be more closely aligned with the requirements for share-based payments granted to employees. The standard is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, but no earlier than the Company's adoption date of ASC 606. The Company adopted the standard on a prospective basis in the third quarter of 2018 and the adoption did not have a material impact on the Company’s financial statements.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, Leases, which amends the existing accounting standards for leases. In September 2017, the FASB issued ASU No. 2017-13 which provides additional clarification and implementation guidance on the previously issued ASU No. 2016-02. Under the new guidance, a lessee will be required to recognize a lease liability and right-of-use asset for all leases with terms in excess of twelve months. The new guidance also modifies the classification criteria and accounting for sales-type and direct financing leases, and requires additional disclosures to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. Consistent with current guidance, a lessee’s recognition, measurement, and presentation of expenses and cash flows arising from a lease will continue to depend primarily on its classification. In July 2018, the FASB issued ASU No. 2018-10 and ASU No. 2018-11, which further clarifies the

application of the guidance issued under ASU No. 2016-02 and provides updates to transition methods and practical expedients. ASU No. 2018-11 provides an optional transition method in addition to the existing transition method which allows entities, at the adoption date, to recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. The accounting standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption is permitted.

The Company has completed its initial assessment of the impact of the new leasing standard on the Company's financial statements and internal controls; including its evaluation of key policy elections. The Company intends to adopt the new standard and related amendments under the optional transitional method as of January 1, 2019. Under this method, the Company is allowed to record a cumulative-effect adjustment to the opening balance of retained earnings in the period of

adoption and not restate prior periods. Additionally, the Company expects to elect the transitional practical expedients such that the Company will not reassess whether contracts are leases and will retain lease classification and initial direct costs for leases existing prior to the adoption of the new standard. The Company also expects to make the following transitional practical expedients elections: (1) elect the short term lease exception, (2) not elect hindsight and (3) elect to not separate its nonlease components for its real estate, vehicle and equipment leases. While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASC 842 on the Company's financial statements, disclosures, and internal controls. The Company estimates its total assets and total liabilities on the consolidated balance sheet will increase by approximately $38.0 million to $46.0 million due to the recognition of right-of-use assets and lease liabilities upon adoption, net of the impact of eliminating existing deferred rent liabilities and pre-paid assets related to its leasing arrangements. This estimated range is based on the Company's current lease portfolio but could be impacted by changes to the lease portfolio, including the total number of leases, lease commencement and end dates and lease termination expectations, as well as changes in anticipated lease incremental borrowing rates. The Company does not expect the adoption of ASU No. 2016-02, as amended, to have a material impact to the Company's consolidated statements of operations or consolidated statements of cash flows.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The Company will recognize an allowance for credit losses on available-for-sale securities rather than deductions in amortized cost. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company is currently evaluating the impact of adopting this standard.

In August 2018, the FASB issued ASU 2018-13, Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The primary focus of the standard is to improve the effectiveness of the disclosure requirements for fair value measurements. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. An entity is permitted to early adopt the removed or modified disclosures upon the issuance of the standard and may delay adoption of the additional disclosures until their effective date. The Company is currently evaluating the impact of adopting this standard.

3. Investments and Fair Value of Financial Instruments

Marketable Investments

The Company's marketable investments have been classified and accounted for as available-for-sale. The Company's marketable investments as of December 31, 2018 and 2017 were as follows (in thousands):

	December 31, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$13,701	$ —	$ (3)	$13,698
U.S. treasury	6,400	—	(22)	6,378
U.S. agency securities and government sponsored securities	7,699	18	(27)	7,690
U.S. states and municipalities	5,134	—	(12)	5,122
Corporate bonds	100,606	14	(469)	100,151
Total	$133,540	$ 32	$ (533)	$133,039

	December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$19,941	$ —	$ (8)	$19,933
U.S. treasury	6,402	—	(28)	6,374
U.S. agency securities and government sponsored securities	4,787	—	(18)	4,769

U.S. states and municipalities	12,510	—	(23)	12,487
Corporate bonds	120,648	23	(280)	120,391
Total	$164,288	$ 23	$ (357)	$163,954

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Notes to Consolidated Financial Statements (Continued)

The following tables present the gross unrealized losses and the fair value for those marketable investments that were in an unrealized loss position for less than and more than twelve months as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018					
	Less than 12 months		More than 12 months		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Commercial paper	$12,208	$ (3)	$—	$ —	$12,208	$ (3)
U.S. treasury	—	—	6,378	(22)	6,378	(22)
U.S. agency securities and government sponsored securities	1,436	(5)	2,759	(22)	4,195	(27)
U.S. states and municipalities	1,529	(5)	3,593	(7)	5,122	(12)
Corporate bonds	58,961	(176)	33,215	(293)	92,176	(469)
Total	$74,134	$ (189)	$45,945	$ (344)	$120,079	$ (533)

	December 31, 2017					
	Less than 12 months		More than 12 months		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Commercial paper	$19,933	$ (8)	$—	$ —	$19,933	$ (8)
U.S. treasury	6,374	(28)	—	—	6,374	(28)
U.S. agency securities and government sponsored securities	2,778	(9)	1,991	(9)	4,769	(18)
U.S. states and municipalities	10,092	(23)	—	—	10,092	(23)
Corporate bonds	93,284	(188)	10,201	(92)	103,485	(280)
Total	$132,461	$ (256)	$12,192	$ (101)	$144,653	$ (357)

The contractual maturities of the Company’s marketable investments as of December 31, 2018 and 2017 were as follows (in thousands):

	December 31,	
	2018	2017
Marketable Investments	Fair Value	Fair Value
Due in one year	$83,391	$104,272
Due in one to five years	49,648	59,682
Total	$133,039	$163,954

Non-Marketable Equity Investments

In the second quarter of 2017, the Company and Sixense Enterprises, Inc. (“Sixense”) formed MVI as a privately-held joint venture for the purpose of exploring healthcare applications of virtual reality technology, with each party holding 50% of the issued and outstanding equity of MVI. On August 31, 2018 (“Transfer Agreement Closing Date”), the Company entered into a Stock Transfer Agreement (the “Transfer Agreement”) between the Company, MVI and Sixense, to purchase an additional 40% of the equity interest in MVI from Sixense for an initial cash purchase price of $20.0 million, excluding the additional $4.5 million of probable future payments relating to an anti-dilution provision in the Transfer Agreement. Following the Transfer Agreement Closing Date, the Company owns a 90% controlling interest in MVI and Sixense retains the remaining 10% minority interest.

Prior to the Transfer Agreement Closing Date, the Company accounted for its investment in MVI under the equity method and was not required to consolidate MVI and determined that MVI was not a variable interest entity (“VIE”). Furthermore, pursuant to agreements between the parties at the time of MVI’s formation, the Company was obligated to perform certain services or make additional cash contributions to MVI for no additional equity interest. These services included, but were not limited to, information technology, accounting, other administrative services and research and development. The Company’s

contributions made prior to the Transfer Agreement Closing Date are presented as a component of the "Contributions to non-marketable investments" in the consolidated statements of cash flows.

As of December 31, 2017, the carrying value of the non-marketable equity investment was approximately $3.9 million, representing the Company's contributions to MVI offset by the Company's share of equity method investee losses, and is presented in long-term investments on the consolidated balance sheet. For the year ended December 31, 2017, MVI had no revenue and recorded a net loss of $2.9 million. For the eight months ended August 31, 2018, prior to the Transfer Agreement Closing Date, MVI had no revenue and recorded a net loss of $6.2 million. The Company reflected its 50% share of MVI's losses as equity in losses of unconsolidated investee in the consolidated statements of operations through the Transfer Agreement Closing Date.

Prior to the Transfer Agreement Closing Date, the unconsolidated balance sheet of MVI had total assets of $5.2 million, total liabilities of $1.0 million and total equity of $4.2 million. As of December 31, 2017, the unconsolidated balance sheet of MVI primarily consists of cash remaining from the initial investment and intangible assets totaling $7.9 million.

Impact of Transfer Agreement on Non-Marketable Equity Investments

The Company accounted for the Transfer Agreement as an asset acquisition, as it was determined that the transaction did not meet the definition of a business under the framework of the authoritative accounting guidance for business combinations. The total consideration transferred has been allocated to the non-monetary assets acquired and liabilities assumed based on their relative fair value.

The following table presents the components of the consideration transferred at fair value as of the Transfer Agreement Closing Date (amounts presented in thousands):

	Amount
Cash transferred	$20,000
Anti-dilution protection at Transfer Agreement Closing Date	4,500
Carrying amount of Penumbra's equity method investment in MVI	2,202
Fair value of the remaining non-controlling interest	3,365
Total consideration transferred	$30,067

In addition to the cash transferred, the consideration included a probable contingent liability related to an anti-dilution provision whereby the Company may be obligated to contribute funds for the issuance of additional shares of MVI to Sixense with an aggregate value of up to $4.5 million. During the year ended December 31, 2018, the Company contributed $0.5 million to MVI related to the anti-dilution provision. As of December 31, 2018, the current and non-current portion of the related liability was $1.5 million and $2.5 million, respectively. The consideration transferred also included the $2.2 million carrying amount of the Company's equity method investment in MVI as of the Transfer Agreement Closing Date, which was written-off as part of the accounting for the Transfer Agreement. The Company also recorded $3.4 million in non-controlling interest on the consolidated financial statements related to the fair value of the remaining minority interest held by Sixense as of the Transfer Agreement Closing Date.

The primary asset acquired in the Transfer Agreement constitutes an in-process research and development asset ("IPR&D"). Due to the nature of the other assets acquired and liabilities assumed, the difference between the fair value of the consideration transferred and the fair value of the tangible net liabilities acquired was allocated solely to the IPR&D. The Company recorded a charge of $30.8 million to acquired in-process research and development expense in the consolidated statements of operations at the Transfer Agreement Closing Date because the Company determined that (1) the IPR&D asset had not yet reached technological feasibility and MVI had not yet obtained the appropriate regulatory approval for any products and (2) the asset had no alternative future use as of the Transfer Agreement Closing Date. Following the Transfer Agreement Closing Date, the financial results of MVI have been consolidated into the accompanying consolidated financial statements, with the amounts attributable to the non-controlling interest classified separately.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:
Level 1 - Quoted prices in active markets for identical assets or liabilities.

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Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.
The categorization of a financial instrument within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement.
The Company classifies its cash equivalents and marketable investments within Level 1 and Level 2, as it uses quoted market prices or alternative pricing sources and models utilizing market observable inputs.
The Company determined the fair value of its Level 1 financial instruments, which are traded in active markets, using quoted market prices for identical instruments.
Marketable investments classified within Level 2 of the fair value hierarchy are valued based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, historical pricing trends of a security as relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy.
The following tables set forth the Company's financial assets and liabilities measured at fair value by level within the fair value hierarchy (in thousands):

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets				
Cash equivalents:				
Commercial paper	$—	$10,967	$—	$10,967
Money market funds	12,087	—	—	12,087
Marketable investments:				
Commercial paper	—	13,698	—	13,698
U.S. treasury	6,378	—	—	6,378
U.S. agency and government sponsored securities	—	7,690	—	7,690
U.S. states and municipalities	—	5,122	—	5,122
Corporate bonds	—	100,151	—	100,151
Total	$18,465	$137,628	$—	$156,093
Financial Liabilities:				
Contingent consideration obligations	$—	$—	$2,571	$2,571
Total	$—	$—	$2,571	$2,571

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	As of December 31, 2017			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets				
Cash equivalents:				
Commercial paper	$—	$9,185	$—	$9,185
Money market funds	2,264	—	—	2,264
Marketable investments:				
Commercial paper	—	19,933	—	19,933
U.S. treasury	6,374	—	—	6,374
U.S. agency and government sponsored securities	—	4,769	—	4,769
U.S. states and municipalities	—	12,487	—	12,487
Corporate bonds	—	120,391	—	120,391
Total	$8,638	$166,765	$—	$175,403
Financial Liabilities:				
Contingent consideration obligations	$—	$—	$4,675	$4,675
Total	$—	$—	$4,675	$4,675

Contingent Consideration Obligations

As of December 31, 2018 and December 31, 2017, the Company's contingent consideration liability relates to milestone payments due in connection with the acquisition of Crossmed and is classified as a Level 3 measurement for which fair value is derived from various inputs, including forecasted revenues during the earn-out milestone periods, revenue volatilities, discount rates, and estimates in the timing and likelihood of achieving revenue-based milestones. The fair value of the contingent consideration liability is remeasured each reporting period. Of the $2.6 million contingent consideration liability as of December 31, 2018, $1.3 million relates to a liability based on actual revenue performance for the year ended December 31, 2018 and is not based on unobservable inputs. Accordingly, only the portion of the contingent consideration liability based on unobservable inputs is included in the table below. The following table presents quantitative information about certain unobservable inputs used in the Level 3 fair value measurement of the Company's contingent consideration liability, other than the forecasted revenues during the earn-out milestone period:

	Fair Value at December 31, 2018 (in thousands)	Valuation Method	Unobservable Inputs	Inputs
Crossmed:				
Revenue-based milestones	$ 1,268	Monte Carlo Simulation	Earn-out period over which revenue-based milestone payments are made	2019
			Risk-adjusted discount rate	15%
			Revenue volatilities for each type of revenue-based milestone	5.1% and 18.4%

The following table summarizes the changes in fair value of the contingent consideration obligation for the year ended December 31, 2018 (in thousands):

	Fair Value of Contingent Consideration
Balance at December 31, 2017	$ 4,675
Payments of contingent consideration liabilities	(3,017)
Changes in fair value	950
Foreign currency remeasurement	(37)

Balance at December 31, 2018	$ 2,571

During the year ended December 31, 2018, the fair value of the contingent consideration obligation increased by $1.0 million, which was recorded in sales, general and administrative expense in the consolidated statements of operations. The fair value of the contingent consideration increased as a result of updates to the underlying forecasts based on actual results to date and changes in estimates. For more information refer to Note “5. Business Combination.”

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During the years ended December 31, 2018, 2017, and 2016, the Company did not record impairment charges related to its marketable investments and the Company did not hold any Level 3 marketable investments as of December 31, 2018 and 2017. During the year ended December 31, 2018 and 2017, the Company did not have any transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy. Additionally, the Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2018 and 2017.

4. Balance Sheet Components

Accounts Receivable, Net

The Company's allowance for doubtful accounts comprised of the following (in thousands):

	Balance At Beginning Of Year	Charged To Costs And Expenses	Deductions[1]	Balance At End Of Year
For the year ended:				
December 31, 2016	$ 589	$ 216	$ (121)	$ 684
December 31, 2017	684	606	—	1,290
December 31, 2018	1,290	1,563	(71)	2,782

[1] Represents the effect of currency translation adjustments and write-offs of uncollectible accounts, net of recoveries.

Inventories

The components of inventories consisted of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$18,829	$13,529
Work in process	10,630	6,073
Finished goods	86,282	75,299
Inventories	$115,741	$94,901

Property and Equipment, Net

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

	December 31,	
	2018	2017
Machinery and equipment	$15,400	$12,456
Furniture and fixtures	7,140	6,458
Leasehold improvements	17,665	15,926
Software	4,095	3,547
Computers	3,289	1,737
Construction in progress	3,234	1,326
Total property and equipment	50,823	41,450
Less: Accumulated depreciation and amortization	(15,416)	(10,551)
Property and equipment, net	$35,407	$30,899

Depreciation and amortization expense, excluding intangible assets, was $5.1 million, $3.4 million and $2.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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Accrued Liabilities

The following table shows the components of accrued liabilities as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018	December 31, 2017
Payroll and employee-related expenses	$ 33,838	$ 22,001
Accrued expenses	4,088	3,927
Sales return reserve	2,986	3,035
Product warranty	1,875	1,088
Contingent consideration & other acquisition-related costs[1]	4,439	4,752
Other accrued liabilities	10,660	10,022
Total accrued liabilities	$ 57,886	$ 44,825

[1] Acquisition-related costs consist of the current portion of contingent liabilities related to (1) the cash milestone payments and working capital adjustment liabilities for the acquisition of Crossmed and (2) an anti-dilution provision for the asset acquisition of MVI. Refer to Note “5. Business Combination” for more information on the acquisition of Crossmed and Note “3. Investments and Fair Value of Financial Instruments” for more information on the MVI asset acquisition.

The following table shows the changes in the Company’s estimated product warranty accrual, included in accrued liabilities, as of December 31, 2018, 2017 and 2016 (in thousands):

	December 31,		
	2018	2017	2016
Balance at the beginning of the year	$1,088	$1,254	$713
Accruals of warranties issued	1,336	471	1,176
Settlements of warranty claims	(549)	(637)	(635)
Balance at the end of the year	$1,875	$1,088	$1,254

Other Non-Current Liabilities

The following table shows the components of other non-current liabilities as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018	2017
Deferred tax liabilities	$4,171	$3,299
Licensing-related cost[1]	11,506	12,717
Asset acquisition-related costs[2]	2,500	—
Other non-current liabilities	766	2,462
Total other non-current liabilities	$18,943	$18,478

[1] Amount relates to the non-current liability recorded for probable future milestone payments to be made under the licensing agreement described in Note “6. Intangible Assets.” Refer therein for more information.

[2] Asset acquisition-related costs represents the non-current portion of the probable contingent liability related to an anti-dilution provision for the asset acquisition of MVI. Refer to Note “3. Investments and Fair Value of Financial Instruments” for more information on the MVI asset acquisition.

5. Business Combination

On July 3, 2017 (the “Closing Date”), the Company completed the acquisition of Crossmed, a joint stock company organized under the laws of Italy. Crossmed is engaged in the business of distributing medical supplies and equipment in Italy, San Marino, Vatican City and Switzerland. Crossmed was the Company’s exclusive distributor in Italy, San Marino, and Vatican City and the acquisition provides the Company with a direct relationship with its customers in these regions. As of the Closing Date, Crossmed became a wholly-owned subsidiary of the Company and was

integrated into the Company’s core

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business. The acquisition of Crossmed did not result in any changes to the Company's operating or reportable segment structure and the Company continues to operate as one operating segment.

The following table summarizes the Closing Date fair value of the consideration transferred, reflecting the measurement period adjustments recorded in the fourth quarter of 2017 (in thousands):

	Fair Value of Consideration Transferred
Cash, net of working capital and financial debt adjustments	$ 11,088
Fair value of contingent consideration for milestone payments	4,343
Contract purchase price	$ 15,431
Consideration for settlement of pre-existing receivable due from Crossmed to Penumbra	3,273
Total value of consideration transferred	$ 18,704

On the Closing Date, the Company paid the sellers of Crossmed an initial payment of €8.2 million, or approximately $9.4 million, subject to post-closing adjustments for working capital and financial debt. The Company is also obligated to pay additional consideration in the form of milestone payments based on Crossmed's net revenue and may be required to pay additional consideration based on incremental net revenue, for the year ended December 31, 2017, and each of the years ending December 31, 2018 and 2019. There is no limit on the milestone payments that can be paid out. As of December 31, 2017, the fair value of the current and non-current portion of the related liabilities for the future cash milestone payments on the consolidated balance sheet was $2.9 million and $1.7 million, respectively. As of December 31, 2018, the fair value of the liability related to the future cash milestone payments was $2.6 million and was classified as a current liability on the consolidated balance sheet. For more information with respect to the nature and fair value of the Company's contingent consideration obligations, refer to Note "3. Investments and Fair Value of Financial Instruments."

During the year ended December 31, 2018, the Company made $4.5 million in cash payments to the Sellers, of which $3.0 million related to the achievement of the 2017 milestones and the remainder related to working capital and financial debt adjustments. These payments have been presented as a component of financing activities in the consolidated statement of cash flows due to the nature and timing of the payments.

The purchase price measurement period was closed as of June 30, 2018. The following table presents the allocation of the purchase price for Crossmed, reflecting the measurement period adjustments recorded in 2017 (in thousands):

	Acquisition-Date Fair Value	Estimated Useful Life of Finite-Lived Intangible Assets
Tangible assets acquired and (liabilities) assumed:		
Accounts receivable	$ 4,406	
Inventories	1,343	
Other current and non-current assets[(1)]	1,596	
Property and equipment, net	829	
Accounts payable	(740)	
Accrued liabilities and obligations for short-term debt and credit facilities[(1)]	(1,868)	
Deferred tax liabilities	(2,472)	
Other non-current liabilities	(797)	
Intangible assets acquired:		
Customer relationships	$ 6,790	15 years
Other	1,750	5 years
Goodwill[(1)]	7,867	
Total purchase price[(1)]	$ 18,704	

(1) During the fourth quarter of 2017, the Company recorded $1.2 million in measurement period adjustments which increased the purchase price, primarily related to working capital and financial debt adjustments.

Acquired intangible assets are classified as Level 3 measurements for which fair value is derived from valuations based on inputs that are unobservable and significant to the overall fair value measurement. The Company used the income approach,

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specifically the discounted cash flow method and the incremental cash flow approach, to derive the fair value of the customer relationships and other intangible assets. Customer relationships are direct relationships with physicians and hospitals performing procedures with the distributed products. Other intangibles consists of non-Penumbra supplier relationships and sub-distributor relationships with third parties used to sell products, both as of the Closing Date. The intangible assets are amortized on a straight-line basis over their assigned estimated useful lives. The amortization of the acquired intangible assets are not deductible for tax purposes. As a result, a $2.5 million deferred tax liability was recorded as of the Closing Date.

The goodwill arising from the Crossmed acquisition is primarily attributed to expected synergies from future growth and assembled workforce. Goodwill is not deductible for tax purposes.

Crossmed's net revenue in the Company's consolidated statements of operations was $6.2 million for the year ended December 31, 2017. Crossmed's net income included in the Company's consolidated statements of operations was $0.2 million for the year ended December 31, 2017.

The following table presents certain unaudited pro forma information, for illustrative purposes only, for the years ended December 31, 2017 and 2016, as if Crossmed had been acquired on January 1, 2016. The unaudited estimated pro forma information combines the historical results of Crossmed with the Company's consolidated historical results and includes certain pro forma adjustments, including intangible asset amortization and the elimination of pre-acquisition sales Penumbra made to Crossmed for the respective periods. The pro forma information may not be indicative of what would have occurred had the acquisition taken place on January 1, 2016, and may not be indicative of the Company's future consolidated results. Additionally, the pro forma financial information does not include the impact of possible business model changes and does not reflect pro forma adjustments to conform accounting policies between Crossmed and the Company. The unaudited pro forma information is presented below (unaudited, in thousands):

	December 31,	
	2017	2016
Pro forma net revenue	$336,557	$268,262
Pro forma net income	5,992	14,816

6. Intangible Assets

The following table presents details of the Company's acquired finite-lived and indefinite-lived intangible assets as of December 31, 2018 and December 31, 2017, (in thousands, except weighted-average amortization period):

As of December 31, 2018	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Net
Customer relationships	15.0 years	$6,823	$ (681)	$6,142
Trade secrets and processes	20.0 years	5,256	(263)	4,993
Other	5.0 years	1,759	(528)	1,231
Total intangible assets subject to amortization	16.0 years	$13,838	$ (1,472)	$12,366
Intangible assets related to licensed technology		14,879	—	14,879
Total intangible assets		$28,717	$ (1,472)	$27,245

As of December 31, 2017	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Net
Customer relationships	15.0 years	$7,141	$ (238)	$6,903
Other	5.0 years	1,841	(183)	1,658
Total intangible assets subject to amortization	13.1 years	$8,982	$ (421)	$8,561
Intangible assets related to licensed technology		15,217	—	15,217

Total intangible assets	$ 24,199	$ (421)	$ 23,778

The customer relationships and other intangible assets subject to amortization relate to the Company's acquisition of Crossmed during the third quarter of 2017. The gross carrying amount and accumulated amortization of these intangible assets are subject to foreign currency translation effects. Refer to Note "5. Business Combination" for more information. The

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Company's trade secrets and processes intangible asset was recognized in connection with a royalty buyout agreement during the first quarter of 2018, which is discussed further in Note "8. Commitments and Contingencies" and Note "9. Stockholders' Equity." The Company's licensed technology intangible asset is discussed further below in this footnote.
The following table presents the amortization recorded related to the Company's finite-lived intangible assets (in thousands)

	Year Ended December 31,	
	2018	2017
Cost of revenue	$263	$—
Sales, general and administrative	832	418
Total	$1,095	$418

The Company did not hold any intangible assets during the year ended December 31, 2016.
As of December 31, 2018, expected amortization expense for the unamortized acquired intangible assets for the next five years and thereafter is as follows (in thousands):

	Amortization Expense
2019	$ 1,069
2020	1,069
2021	1,069
2022	894
2023	718
Thereafter	7,547
Total amortization	$ 12,366

Licensed technology
During the third quarter of 2017, the Company entered into an exclusive technology license agreement (the "License Agreement") that required the Company to pay an upfront payment to the licensor of $2.5 million and future revenue milestone-based payments on sales of products covered by the licensed intellectual property. The Company recorded an intangible asset equal to the total payments made and expected to be made under the License Agreement and a corresponding contingent liability for the probable future milestone payments not yet paid. As of December 31, 2018, the licensed technology is accounted for as an indefinite-lived intangible asset. Upon the commercialization of the underlying product utilizing the licensed technology, the capitalized amount will be amortized over its estimated useful life.
At the end of each reporting period the Company adjusts the contingent liabilities to reflect the amount of future milestone payments that are probable to be paid. Prior to the commercialization of products utilizing the underlying technology, any changes in the contingent liability are recorded as an adjustment between the liability balances and the gross carrying amount of the indefinite-lived intangible asset. During the year ended December 31, 2018, the contingent liability related to the exclusive technology license agreement decreased by $0.3 million. The changes in the contingent liability balance were due to changes in the underlying revenue forecasts used to estimate the probable future milestone payments. As of December 31, 2018, the balance of the contingent liability related to probable future milestone payments under the Licensing Agreement was $12.4 million, of which $0.9 million and $11.5 million were included in accrued liabilities and other non-current liabilities on the consolidated balance sheet, respectively. As of December 31, 2017, the balance of the contingent liability related to probable future milestone payments under the Licensing Agreement was $12.7 million which was included in other non-current liabilities on the consolidated balance sheet.
As of December 31, 2018, the gross carrying amount of the indefinite-lived intangible asset was $14.9 million. The Company completed its annual impairment analysis of its indefinite-lived intangible asset during the fourth quarter of

2018 and determined that there was no impairment of the indefinite-lived intangible asset.

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7. Goodwill

The following table presents the changes in goodwill during the year ended December 31, 2018 (in thousands):

	Total Company
Balance as of December 31, 2017	$ 8,178
Foreign currency translation adjustments	(365)
Balance as of December 31, 2018	$ 7,813

Goodwill Impairment Review

The Company reviews goodwill for impairment annually during the fourth quarter, on October 31st, or more frequently if events or circumstances indicate that an impairment loss may have occurred. The Company determined that based on its organizational structure and the availability of discrete financial information regularly reviewed that there is only one reporting unit at the consolidated level as of and for the years ending December 31, 2018 and 2017. During the fourth quarter of 2018 and 2017, the Company reviewed goodwill for impairment and no impairment was identified.

8. Commitments and Contingencies

Lease Commitments

The Company leases its offices primarily under non-cancelable operating leases that expire at various dates through 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 corporate headquarters' campus becomes vacant, that space will be added to the lease at the then current base monthly rental rate. The maximum additional space that could be added under this provision of the lease as of December 31, 2018, is approximately 100,000. The additional space could potentially result in approximately $1.6 million of annual rent expense based on current terms of the lease. The table below does not include the Company's potential obligation for the additional space(s) that may be added to the lease by the landlord. The Company leases other equipment and vehicles primarily under non-cancelable operating leases that expire at various dates through 2023.

During the third quarter of 2018, the Company signed a fifteen year lease for approximately 160,000 square feet to serve as a manufacturing facility in Roseville, California (the "Roseville Lease"). The lease is expected to commence upon substantial completion of the improvements to the building, which the Company anticipates will be completed within the next two years. The total estimated lease payments over the fifteen year lease term is approximately $40.9 million. The Company has an option to renew for an additional five to ten years.

Rent expense for the years ended December 31, 2018, 2017 and 2016 was $5.8 million, $5.8 million and $5.2 million, respectively. In addition to the amounts included in the table below, certain lease agreements require the Company to make payments during the lease term for taxes, insurance and other operating expenses.

Future minimum lease payments under the non-cancelable leases as of December 31, 2018 are as follows (in thousands):

	Lease Payments[(1)]
Year Ending December 31:	
2019	$ 6,575
2020	6,571
2021	5,809
2022	5,772
2023	5,735
Thereafter	40,194
Total future minimum lease payments	$ 70,656

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(1) The table above excludes the estimated future minimum lease payment for the Company's Roseville Lease, due to the uncertainty around the timing of when the lease will commence and payments will be due.

Purchase Commitments

As of December 31, 2018, the Company had non-cancelable purchase obligations to suppliers of $23.1 million.

Royalty Obligations

In March 2005, the Company entered into a license agreement that requires the Company to make minimum royalty payments to the licensor, on a quarterly basis. As of December 31, 2018, 2017 and 2016, the license agreement requires minimum annual royalty payments of $0.1 million in equal quarterly installments. On each January 1, the quarterly calendar year minimum royalty shall be adjusted to equal the prior year's minimum royalty adjusted by a percentage equal to the percentage change in the "consumer price index for all urban consumers" for the prior calendar year as reported by the U.S. Department of Labor. Unless terminated earlier, the term of the license agreement shall continue until the expiration of the last to expire patent that covers that licensed product or for the period of fifteen years following the first commercial sale of such licensed product, whichever is longer. The first commercial sale of covered products occurred in June 2007.

In April 2012, the Company entered into an agreement that requires the Company to pay, on a quarterly basis, a 5% royalty on sales of products covered under applicable patents. The first commercial sale of covered products occurred in April 2014. Unless terminated earlier, the royalty term for each applicable product shall continue for fifteen years following the first commercial sale of such patented product, or when the applicable patent covering such product has expired, whichever is sooner.

In November 2013, the Company entered into an agreement that requires the Company to pay, on a quarterly basis, a 3% royalty on the first $5 million in sales and a 1% royalty on sales thereafter of products covered under applicable patents. The agreement was terminated effective January 1, 2018.

In April 2015, the Company entered into a royalty agreement that required the Company to pay a 2% royalty on sales of certain products covered by the agreement, on a quarterly basis, in exchange for certain trade secrets and processes which were used to develop such covered products. The Company began the first commercial sale of the covered products in July 2015. In the first quarter of 2018, the Company entered into a buyout of this agreement (the "Buyout Agreement") in which future royalty payments were canceled in exchange for shares of the Company's common stock with a fair value of $5.3 million. The Company recorded an intangible asset equal to the $5.3 million buyout amount which will be amortized into cost of sales over the period in which the Company receives future economic benefit. After determining that the pattern of future cash flows associated with this intangible asset could not be reliably estimated with a high level of precision, the Company concluded that the intangible asset will be amortized on a straight line basis over its estimated useful life. For more information refer to Note "6. Intangible Assets" and Note "9. Stockholders' Equity."

Royalty expense included in cost of sales for the years ended December 31, 2018, 2017 and 2016 was $3.4 million, $4.1 million and $2.9 million, respectively.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. Refer to Note "6. Intangible Assets" for more information on contingent liabilities recorded on the consolidated balance sheet.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. In many such arrangements, the Company agrees to indemnify, hold harmless, and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to the Company's technology. The Company also agrees to indemnify many purchasers for product defect and similar claims. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required

to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

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The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. No liability associated with any of these indemnification requirements has been recorded to date.

Litigation

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

9. Stockholders' Equity

Stockholders' Equity

Preferred Stock

The Company has 5,000,000 of authorized preferred stock issuable. There is no preferred stock outstanding as of December 31, 2018 and 2017.

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding.

In the first quarter of 2018, the Company issued 53,256 fully vested restricted stock units with a fair value of $5.3 million in connection with the Buyout Agreement, as discussed in Note "6. Intangible Assets" and Note "8. Commitments and Contingencies." The Company recorded the $5.3 million fair value of the shares issued to additional-paid in capital on the consolidated balance sheet upon the issuance of the awards, with the associated expense being amortized into cost of sales over the period in which the Company receives future economic benefit from the buyout.

Issuance of Common Stock in Public Offerings

In March 2017, the Company issued and sold an aggregate of 1,495,000 shares of common stock at a public offering price of $76.00 per share, less the underwriters' discounts and commissions, pursuant to an underwritten public offering. The Company received approximately $106.3 million in net cash proceeds after deducting underwriting discounts and commissions of $6.8 million and other offering expenses of $0.5 million.

Stock-Based Benefit Plans

2005 Stock Plan

The Company adopted the Penumbra, Inc. 2005 Stock Plan ("the 2005 Plan") in January 2005. The 2005 Plan was subsequently amended and restated in 2006, 2007, 2008 and 2010. Under the 2005 Plan, the board of directors could grant incentive stock options ("ISOs"), nonqualified stock options ("NSOs"), and/or stock awards to eligible persons, including employees, nonemployees, directors, consultants and other independent advisors who provide services to the Company. Stock purchase rights could also be granted under the 2005 Plan. The board of directors had the authority to determine to whom options would be granted, the number of options, the term and the exercise price. ISOs could only be granted to Company employees, which include officers and directors of the Company. NSOs and stock purchase rights could be granted to employees and consultants. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price for an ISO could not be less than 110% of fair market value. Options granted under the 2005 Plan permitted an optionee to exercise options immediately upon grant irrespective of the vesting term. Options generally vest annually at a rate of 1/4 after the first year and 1/48 per month thereafter. The term of the options is no longer than five years for ISOs, for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than 10 years for all other options. On September 17, 2015, the 2014 Equity Incentive Plan (as amended and restated, the 2014 Plan) replaced the 2005 Plan and no further equity awards may be granted under the 2005 Plan. The remaining 564 shares of common stock available for issuance from the 2005 Plan were transferred to and may be granted under the 2014 Plan. As of December 31, 2018, 267,577 shares of common stock were reserved for issuance under the 2005 Plan.

2011 Equity Incentive Plan

The Company adopted the Penumbra, Inc. 2011 Equity Incentive Plan (“the 2011 Plan”) in October 2011. Under the 2011 Plan, the board of directors could grant ISOs, NSOs, restricted stock, and/or RSUs to eligible persons, including employees,

directors and consultants who provide services to the Company. Stock Appreciation Rights ("SAR") could also be granted under the 2011 Plan. The board of directors had the authority to determine to whom options would be granted, the number of options, the term and the exercise price. ISOs could only be granted to Company employees, which include officers and directors of the Company. NSOs, SARs, restricted stock and RSUs could be granted to employees and consultants. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price for an ISO could not be less than 110% of fair market value. Stock options granted under the 2011 Plan generally have a contractual life of ten years, and generally vest over a period of four years. On September 17, 2015, the 2014 Plan replaced the 2011 Plan and no further equity awards may be granted under the 2011 Plan. The remaining 89,559 shares of common stock available for issuance from the 2011 Plan were transferred to and may be granted under the 2014 Plan. As of December 31, 2018, 145,000 shares of common stock were reserved for issuance under the 2011 Plan.

Amended and Restated 2014 Equity Incentive Plan

The Company adopted the Penumbra, Inc. 2014 Equity Incentive Plan in May 2014. The plan was amended and restated as of September 17, 2015 (as amended and restated, "the 2014 Plan"). The 2014 Plan replaced the 2011 Plan and the 2005 Plan and no further equity awards may be granted under the 2011 Plan or the 2005 Plan. As of December 31, 2018, 8,614,792 shares of common stock were reserved for issuance and 7,051,991 shares of common stock were available for grant under the 2014 Plan.

Employee Stock Purchase Plan

The Penumbra, Inc. Employee Stock Purchase Plan ("the ESPP'), became effective on September 17, 2015. The ESPP initially reserved 600,000 shares of common stock for purchase under the ESPP, with the number of shares reserved for purchase increasing each year pursuant to an "evergreen" provision set forth in the ESPP. As of December 31, 2018, 1,177,339 shares of common stock were reserved and available for issuance under the plan. All qualifying employees of the Company and its designated subsidiaries are eligible to participate in the ESPP. Each offering to the Company's employees to purchase stock under the ESPP will begin on each May 20 and November 20 and will end on the following November 19 and May 19, respectively, each referred to as offering periods, except that the first offering period under the ESPP began on September 17, 2015 and ended on May 19, 2016. Under the ESPP, each employee may purchase shares by authorizing payroll deductions at a minimum of 1% and up to 15% of his or her eligible compensation for each pay period during the offering period. Unless the participating employee withdraws from the offering, his or her accumulated payroll deductions will be used to purchase the Company's common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the common stock on either the first or the last day of the offering period, whichever is lower, provided that no more than 2,000 shares of the Company's common stock or such other lesser maximum number established by the ESPP administrator may be purchased by any one employee during each offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of common stock, valued at the start of the purchase period (corresponding to an offering period), under the ESPP in any calendar year.

Early Exercises

Stock options granted under the 2005 Plan and 2011 Plans allow the board of directors to grant awards to provide employee option holders the right to elect to exercise unvested options in exchange for restricted common stock. As of December 31, 2017, there were 409 unvested shares, subject to a repurchase right held by the Company at the original issue price in the event the optionees' employment was terminated either voluntarily or involuntarily. As of December 31, 2018, there were no such early exercised unvested shares. For exercises of employee options, this right lapses according to the vesting schedule designated on the associated option grant. The repurchase terms are considered to be a forfeiture provision. The shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued or outstanding for accounting purposes until those shares vest, though they are legally issued and outstanding. In addition, cash received from employees for exercise of unvested options is treated as a refundable deposit shown as a liability on the consolidated balance sheets and are transferred into common stock and additional paid-in-capital as the shares vest.

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Stock-Based Benefit Activity and Stock-Based Compensation
Stock Options
Activity of stock options under the 2005 Plan, 2011 Plan and 2014 Plan is set forth below:

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2017	2,107,104	$ 17.58		
Exercised	(416,209)	12.16		
Canceled/Forfeited	(2,014)	22.04		
Balance at December 31, 2018	1,688,881	$ 18.91		
Vested and expected to vest—December 31, 2018	1,687,771	$ 18.91	5.85	$ 174,337
Exercisable—December 31, 2018	1,454,103	$ 17.99	5.73	$ 151,528

The total intrinsic value of stock options exercised during the year ended December 31, 2018, 2017 and 2016 was $49.1 million, $56.4 million and $53.1 million, respectively. The intrinsic value is calculated as the difference between the estimated fair value of the Company's common stock at the exercise date and the exercise price of the stock option.
The Company did not grant stock options during the years ended December 31, 2018, 2017 and 2016.
Restricted Stock and Restricted Stock Units
The activity of unvested restricted stock and restricted stock units under the Plans is set forth below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	742,405	$ 38.86
Granted	125,446	113.06
Vested	(411,113)	40.69
Canceled/Forfeited	(5,275)	82.68
Unvested at December 31, 2018	451,463	$ 57.29

The fair value of the restricted stock and restricted stock units that vested during the years ended December 31, 2018, 2017 and 2016 was $47.0 million, $29.1 million and $9.9 million, respectively. As of December 31, 2018, 441,166 restricted stock or restricted stock units are expected to vest.
Employee Stock Purchase Plan
Under the Penumbra, Inc. ESPP, employees purchased 74,344, 91,685, and 214,025 shares for $7.2 million, $5.8 million, and $6.6 million during the years ended December 31, 2018, 2017, and 2016 respectively.
Stock-based Compensation
The Company uses the Black-Scholes option pricing model to determine the fair value of stock options and ESPP. The valuation model for stock compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation including the expected term (weighted average period of time that the options granted are expected to be outstanding); volatility of the Company's common stock and an assumed-risk-free interest rate.

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Notes to Consolidated Financial Statements (Continued)

The Company used the following assumptions in its Black-Scholes option pricing model to determine the fair value of equity settled awards:

	Equity Settled Awards Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	0.50	0.50	0.50
Expected volatility	42%	34%	40%
Risk-free interest rate	2.36%	1.26%	0.48%
Expected dividend rate	0%	0%	0%

The assumptions in the table above for fiscal 2018, 2017and 2016, respectively relate only to ESPP.
Weighted Average Expected Term. The Company's expected term for ESPP is in line with the six month look-back period of its ESPP.
Volatility. In 2018, 2017 and 2016, volatility assumptions used in the valuation of ESPP were calculated based on the historical volatility of the Company's stock.
Risk-Free Interest Rate. The risk-free interest rate is based upon U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the options or ESPP shares.
Dividend Yield. The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.
Forfeitures. The Company estimates forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.
The following table sets forth the stock-based compensation expense included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of sales	$1,004	$1,009	$1,132
Research and development	1,597	1,289	1,020
Sales, general and administrative	15,821	15,514	12,485
	$18,422	$17,812	$14,637

As of December 31, 2018, total unrecognized compensation cost was $22.6 million related to unvested share-based compensation arrangements which is expected to be recognized over a weighted average period of 2.1 years.
The total stock-based compensation cost capitalized in inventory was $0.4 million, $0.2 million and $0.4 million as of December 31, 2018, 2017 and 2016, respectively.
10. Accumulated Other Comprehensive (Loss) Income
Other comprehensive (loss) income consists of two components: unrealized gains or losses on the Company's available-for-sale marketable investments and gains or losses from foreign currency translation adjustments. Until realized and reported as a component of net income, these comprehensive (loss) income items accumulate and are included within accumulated other comprehensive (loss) income. Unrealized gains and losses on our marketable investments are reclassified from accumulated other comprehensive (loss) income into earnings when realized upon sale, and are determined based on specific identification of securities sold. Gains and losses from the translation of assets and liabilities denominated in non-U.S. dollar functional currencies are included in accumulated other comprehensive (loss) income.

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

The following table summarizes the changes in the accumulated balances during the period, and includes information regarding the manner in which the reclassifications out of accumulated other comprehensive (loss) income into earnings affect our consolidated statements of comprehensive (loss) income (in thousands):

	Year Ended December 31, 2018			Year Ended December 31, 2017		
	Marketable Investments	Currency Translation Adjustments	Total	Marketable Investments	Currency Translation Adjustments	Total
Balance, beginning of the year	$(235)	$ 1,804	$1,569	$(105)	$ (4,583)	$(4,688)
Other comprehensive (loss) income before reclassifications:						
Unrealized losses — marketable investments	(165)	—	(165)	(133)	—	(133)
Foreign currency translation (losses) gains	—	(3,027)	(3,027)	—	6,387	6,387
Income tax effect — (expense) benefit	(100)	(219)	(319)	31	—	31
Net of tax	(265)	(3,246)	(3,511)	(102)	6,387	6,285
Amounts reclassified from accumulated other comprehensive loss to earnings:						
Realized loss — marketable investments	—	—	—	(37)	—	(37)
Income tax effect — benefit	—	—	—	9	—	9
Net of tax	—	—	—	(28)	—	(28)
Net current-year other comprehensive (loss) income	(265)	(3,246)	(3,511)	(130)	6,387	6,257
Balance, end of the year	$(500)	$ (1,442)	$(1,942)	$(235)	$ 1,804	$1,569

11. Employee Benefit Plan

The Company offers a retirement savings plan under Section 401(k) of the Internal Revenue Code (“IRC”) to its eligible U.S. employees whereby they may contribute up to the maximum amount permitted by the IRC. In the third quarter of 2015, the Company began 401(k) matching of eligible compensation under the plan, subject to a maximum dollar threshold. Contribution expense was $1.6 million, $1.1 million, and $0.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

12. Income Taxes

The Company’s income tax (benefit) expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management’s best assessment of estimated current and future taxes to be paid. The Company is subject to income taxes in both the United States and foreign jurisdictions. Significant judgments and estimates are required in determining the consolidated income tax (benefit) expense.

The Company is incorporated in the United States and operates in various countries with different tax laws and rates. A portion of the Company’s income or (loss) before taxes and the (benefit from) provision for income taxes are generated from international operations.

Income (loss) before income taxes and equity in losses of unconsolidated investee for the years ended December 31, 2018, 2017 and 2016 is summarized as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$(2,790)	$543	$(944)
Foreign	4,398	1,933	75
Total income (loss) before income taxes and equity in losses of unconsolidated investee	$1,608	$2,476	$(869)

Income tax (benefit) or provision in 2018, 2017 and 2016 is comprised of federal, state, and foreign taxes.

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

The components of the (benefit from) provision for income taxes are summarized as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	$290	$(13)	$(3,872)
State	183	259	304
Foreign	1,689	739	772
Total current	$2,162	$985	$(2,796)
Deferred:			
Federal	(5,436)	(2,502)	(11,909)
State	(770)	(1,742)	(785)
Foreign	(359)	(352)	(193)
Total deferred	$(6,565)	$(4,596)	$(12,887)
Benefit from income taxes	$(4,403)	$(3,611)	$(15,683)

The Company’s actual (benefit from) or provision for tax differed from the amounts computed by applying the Company’s U.S. federal statutory income tax rate to pretax income as a result of the following:

	Year Ended December 31,		
	2018	2017	2016
Income tax at federal statutory rate	21.0 %	34.0 %	34.0 %
State income taxes, net of federal benefit	(33.1)	(94.6)	417.1
Foreign taxes differential	37.2	(4.2)	(63.0)
Prepaid tax ASC 810-10	5.0	(39.8)	59.0
IPR&D charge	402.5	—	—
Stock-based compensation	(809.6)	(802.0)	1,474.0
Non-deductible meals and entertainment	31.3	19.4	(92.6)
Imputed interest	19.8	19.1	(30.7)
Tax credits	—	(0.5)	395.5
Remeasurement of deferred tax assets and liabilities	—	622.5	—
Transfer pricing tax benefit	—	(35.3)	—
Global intangible low-taxed income ("GILTI")	14.0	—	—
Contingent liabilities	12.4	—	—
Executive compensation	6.5	—	—
Non-deductible expenses	15.3	—	—
Other	3.9	8.0	(47.4)
Change in valuation allowance	—	127.6	(340.8)
Effective tax rate	(273.8)%	(145.8)%	1,805.1 %

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

Deferred income tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$27,456	$20,622
Tax credits	11,459	7,095
Accruals and reserves	6,078	5,430
Stock-based compensation	3,485	3,083
Translation adjustment	527	486
UNICAP adjustments	4,993	3,813
Other	464	487
Gross deferred tax assets	54,462	41,016
Valuation allowance	(17,284)	(10,295)
Total deferred tax assets	37,178	30,721
Deferred tax liabilities:		
Depreciation and amortization	(6,293)	(6,363)
Total deferred tax liabilities	(6,293)	(6,363)
Net deferred tax assets	$30,885	$24,358

As of December 31, 2018, the Company had approximately $100.0 million, $88.7 million and $0.7 million of federal, state and foreign net operating loss carryforwards, respectively, available to offset future taxable income. The federal net operating loss will begin to expire in 2036. The state net operating loss carryforwards will begin to expire in 2020. As of December 31, 2018, the Company had federal research credits of $6.4 million and California state tax credits of $8.0 million. The federal research credits are generally carried forward for 20 years. California state tax credits may be carried forward indefinitely.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, (the “Tax Reform Act”) was enacted. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, including but not limited to, lowering the U.S. corporate income tax rate to 21% effective January 1, 2018, implementing a territorial tax system, imposing a one-time transition tax on previously untaxed accumulated earnings and profits of foreign subsidiaries, and creating new taxes on foreign sourced earnings. Also on December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin 118 (“SAB 118”), which provides guidance on accounting for tax effects of the Tax Reform Act. SAB 118 provides for a measurement period, that should not extend beyond one year from the Tax Reform Act enactment date, for companies to complete the accounting under ASC 740. In accordance with SAB 118, the Company must reflect the income tax effects of those aspects of the Tax Reform Act for which the accounting under ASC 740 is complete.

As of December 31, 2018, the Company completed its accounting for the tax effects of the Tax Reform Act under ASC 740 and therefore its financial statements reflect estimates based on current interpretations of the authoritative guidance available to date. In the reporting period ended December 31, 2017, the Company recorded an adjustment for the reduction of our U.S. corporate income tax rate to 21% effective January 1, 2018, resulting with a decrease to its DTAs in the amount of $15.4 million with a corresponding charge to income tax expense. No adjustments related to the federal tax rate reduction were made to the Company’s DTA balance subsequent to December 31, 2017. In the reporting period ended December 31, 2018, the Company completed its accounting for the one-time transition tax on the cumulative value of foreign earnings and profits not previously repatriated for U.S. income tax purposes, and completed its analysis of the new GILTI inclusion attributable to foreign sourced earnings. The tax effects of the one-time transition tax and GILTI income inclusion did not have a material impact on the Company’s financial statements as of or for the year ended December 31, 2018. The Company elects to record U.S. taxes due on income inclusions attributable to GILTI as a period cost in the tax year incurred.

The final impact of the Tax Reform Act may differ from the Company's current estimates, due to, among other things, changes in current interpretation and application of the new tax law resulting from additional legislative guidance that may be issued.

The Company generated significant domestic DTAs in recent years, primarily due to the excess tax benefits from stock option exercises and vesting of restricted stock. The Company assessed its ability to realize the benefits of its domestic DTAs by evaluating all available positive and negative evidence, objective and subjective in nature, including (1) cumulative results of operations in recent years, (2) sources of recent pre-tax income, (3) estimates of future taxable income, (4) the length of net

operating loss ("NOL") carryforward periods, and (5) the ability to carry back losses to prior years. The Company determined it would be in a three-year cumulative taxable income position, had it not been for the impact of excess tax deductions from stock-based compensation. The Company also measured its current DTA balances against estimates of future income based on objectively verifiable operating results from the Company's recent history.

The Company considered its projections of future taxable income in conjunction with relevant provisions of the Tax Reform Act, including but not limited to, the indefinite carryforward period for NOLs generated in years beginning on or after January 1, 2018. The Company also considered its three-year cumulative taxable income position, exclusive of the impact of excess tax deductions from stock-based compensation under ASU 2016-09. After an evaluation of all available qualitative and quantitative evidence, both positive and negative in nature, the Company concluded that sufficient future taxable income will be generated to realize the benefits of its federal DTAs prior to expiration other than its federal research and development tax credit DTAs. The tax attribute ordering rules provide that net operating losses must be used in full to offset taxable income prior to the utilization of tax credits. Accordingly, the Company's federal research and development tax credit DTAs, which have a 20 year carryforward period, are expected to expire prior to utilization based on the timing of future projected taxable income. As a result, as of December 31, 2018, the Company maintained a valuation allowance against its federal research and development tax credit.

For years ended December 31, 2018, 2017 and 2016, a full valuation allowance remains against the Company's California DTA balances.

As of December 31, 2018, the Company's DTA balance included $3.0 million of tax attributes gained upon acquisition of a majority interest ownership in MVI. The acquired DTAs are subject to Separate Return Limitation Year ("SRLY") rules which will limit the utilization of the pre-acquisition tax attributes to offset future taxable income solely generated by MVI. As of December 31, 2018, the Company could not conclude, at the required more-likely-than-not level of certainty, that MVI will generate sufficient taxable income to realize the benefit of its tax attributes prior to expiration. As a result, a $3.0 million valuation allowance was recorded against the DTAs acquired from MVI.

The change in the Company's deferred tax valuation allowance against net DTAs changed from January 1, 2016 to December 31, 2018, is as follows (in thousands):

	Beginning Balance	Additions Charged To Expenses or Other Accounts[1]	Deductions Credited to Expenses or Other Accounts[2]	Ending Balance
For the year ended:				
December 31, 2016	$ 2,702	$ 3,360	$ —	$ 6,062
December 31, 2017	6,062	4,400	(167)	10,295
December 31, 2018	10,295	6,989	—	17,284

[1] Additions include current year additions charged to expenses and current year build due to increases in net DTAs, return to provision true-ups, and other adjustments.

[2] Deductions include current year releases credited to expenses and current year reductions due to decreases in net DTAs, return to provision true-ups, and other adjustments.

The Company will continue to closely monitor the need for a valuation allowance against its existing domestic and foreign DTAs and any additional DTAs that are generated in each subsequent reporting period. The need for a valuation allowance can be impacted by actual operating results, forecasted financial performance, variances between the two, and the rate at which future DTAs are generated.

IRC Sections 382 and 383 limit the use of net operating losses and business credits if there is a change in ownership. In 2009, the Company determined there were changes in ownership in 2004 and 2008, which did not cause any impairment of tax attributes.

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A reconciliation of the change in the gross unrecognized tax benefits from January 1, 2016 to December 31, 2018, is as follows (in thousands):

	December 31,		
	2018	2017	2016
Beginning Balance	$4,152	$3,827	$3,619
Gross increase for tax positions of current year	1,421	871	1,213
Gross increase for tax positions of prior years	238	130	250
Gross decrease for tax positions of prior years	(616)	(659)	(648)
Settlement	—	—	(387)
Lapse of statute of limitations	(21)	(17)	(220)
Ending Balance	$5,174	$4,152	$3,827

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. Income tax expense for the years ended December 31, 2018, 2017 and 2016 included interest and penalties that were not material. As of December 31, 2018, 2017 and 2016, the Company had approximately $0.2 million, $0.1 million, and $0.1 million respectively, of accrued interest and penalties attributable to uncertain tax positions. Included in the $5.2 million balance of unrecognized tax benefits as of December 31, 2018 is $1.8 million of tax benefit that, if recognized, would affect the effective tax rate.

The Company files U.S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to net operating loss and credit carryovers, the tax years ending December 31, 2004 through December 31, 2018 remain subject to examination by federal and state tax authorities. In Australia and Canada, tax years ending December 31, 2009 through December 31, 2018 generally remain subject to examination by tax authorities. In Germany and Italy, tax years ending December 31, 2013 through December 31, 2018 remain subject to examination by tax authorities. In the year ended December 31, 2018, the German tax authority initiated an income tax audit for tax years ended December 31, 2014, 2015 and 2016. The Company believes that an adequate provision has been made for any adjustments that may result from the tax examination, however, the audit is in its preliminary stages and so the outcome and timing of resolution is uncertain.

The Company does not anticipate significant changes in the balance of gross unrecognized tax benefits over the next 12 months.

The Company maintains that all foreign earnings, with the exception of a portion of the earnings of its German subsidiary, are permanently reinvested outside the U.S. and therefore deferred taxes attributable to such are not provided for in the Company’s financial statements as of December 31, 2018. The Company will repatriate foreign earnings only to the extent doing so will not result with any material U.S. tax consequences. Thus, deferred taxes on any potential future repatriation of a portion of the earnings of its German subsidiary were not reflected in the Company’s financial statements as of December 31, 2018.

13. Net Income Attributable to Penumbra, Inc. per Share

The Company’s basic net income attributable to Penumbra, Inc. per share is calculated by dividing the net income attributable to Penumbra, Inc. by the weighted average number of shares of common stock outstanding for the period. The diluted net income per share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For the purposes of this calculation, options to purchase common stock, restricted stock, restricted stock units and stock sold through the Company’s employee stock purchase plan are considered common stock equivalents.

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net income per share attributable to common stockholders is as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net income attributable to Penumbra, Inc.	$6,601	$ 4,657	$ 14,814
Denominator:			
Weighted average shares used to compute net income attributable to common stockholders:			
Basic	34,138,137	32,978,065	30,464,583
Potential dilutive stock-based awards, as calculated using treasury stock method	1,948,645	2,341,038	3,013,495
Diluted	36,086,825	35,319,103	33,478,078
Net income attributable to Penumbra, Inc. per share from:			
Basic	$0.19	$ 0.14	$ 0.49
Diluted	$0.18	$ 0.13	$ 0.44

For the years ended December 31, 2018, 2017 and 2016, outstanding stock-based awards of 49 thousand, 54 thousand and 276 thousand shares, respectively, were excluded from the computation of diluted net income per share because their effect would have been anti-dilutive.

14. Revenues

Adoption of ASC Topic 606, “Revenue from Contracts with Customers”

The Company adopted the guidance under ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. Therefore, the comparative prior year information has not been adjusted and continues to be reported under ASC 605 with the impact of the adoption reflected in opening retained earnings. As a result of adoption, the cumulative impact to our retained earnings at January 1, 2018 was $0.3 million. The adoption of ASC 606 represents a change in accounting principle that more closely aligns the timing of revenue recognition with the point in time that a performance obligation is satisfied. The Company’s performance obligations are satisfied at a point in time. The implementation of the new standard did not have a material impact on the measurement or recognition of revenue from prior periods, however additional disclosures have been added in accordance with the guidance.

As required by ASC 606, the impact of adoption of the new revenue standard on the Company's consolidated statements of operations and comprehensive income and consolidated balance sheets was as follows (in thousands):

	As of December 31, 2018		
	As Reported	Adjustments	Adjusted Balance Without 606 Adoption
Consolidated Balance Sheet Data:			
Assets			
Accounts receivable, net of doubtful accounts	$81,896	$ (984)	$ 80,912
Inventories	115,741	343	116,084
Deferred taxes	32,940	181	33,121
Equity			
Retained Earnings	$9,064	$ (460)	$ 8,604

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

	Year Ended December 31, 2018		
	As Reported	Adjustments	Adjusted Balance Without 606 Adoption
Consolidated Income Statement Data:			
Revenue	$444,938	$ (326)	$444,612
Cost of revenue	152,405	(126)	152,279
Loss from operations	(852)	(200)	(1,052)
Income (loss) before income taxes and equity in losses of unconsolidated investee	1,608	(200)	1,408
Benefit from income taxes	(4,403)	(37)	(4,440)
Net income (loss) attributable to Penumbra, Inc.	$6,601	$ (163)	$6,438

Revenue Recognition

Revenue is recognized in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenue recognized in the income statement is considered to be revenue from contracts with customers.

The Company's revenues disaggregated by geography, based on the destination to which the Company ships its products, for the year ended December 31, 2018, 2017 and 2016 was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$290,716	$219,173	$176,104
Japan	41,805	33,790	30,284
Other International	112,417	80,801	56,929
Total	$444,938	$333,764	$263,317

The Company's revenues disaggregated by product category, for the year ended December 31, 2018, 2017 and 2016 was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Neuro	$294,333	$232,446	$185,533
Vascular	150,605	101,318	77,784
Total	$444,938	$333,764	$263,317

Performance Obligations

Delivery of Penumbra products - Penumbra's contracts with customers typically contain a single performance obligation, delivery of Penumbra products. Satisfaction of that performance obligation occurs when control of the promised goods transfers to the customer, which is generally upon shipment for non-consignment sale agreements and upon utilization for consignment sale agreements.

Payment terms - Our payment terms vary by the type and location of our customer. The timing between fulfillment of performance obligations and when payment is due is not significant and does not give rise to financing transactions. The Company did not have any contracts with significant financing components as of December 31, 2018.

Product returns - The Company may allow customers to return products purchased at the Company's discretion. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using its own historic sales information, trends, industry data, and other relevant data points.

Warranties - Penumbra offers its standard warranty to all customers and it is not available for sale on a standalone basis. Penumbra's standard warranty represents its guarantee that its products function as intended, are free from

defects, and comply

with agreed-upon specifications and quality standards. This assurance does not constitute a service and is not a separate performance obligation.

Transaction Price

Revenue is recorded at the net sales price, which includes estimates of variable consideration such as product returns utilizing historical return rates, rebates, discounts, and other adjustments to net revenue. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price. When determining if variable consideration should be constrained, management considers whether there are factors that could result in a significant reversal of revenue and the likelihood of a potential reversal. Variable consideration is included in revenue only to the extent that it is probable that a significant reversal of the revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required. During the year ended December 31, 2018, the Company made no changes in estimates for variable consideration. When the Company performs shipping and handling activities after control of goods is transferred to the customer, they are considered as fulfillment activities, and costs are accrued for when the related revenue is recognized. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues.

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Penumbra, Inc.
Notes to Consolidated Financial Statements (Continued)

15. Selected Quarterly Financial Data (Unaudited)
The following tables provide the selected quarterly financial data for 2018 and 2017 (in thousands, except share and per share amounts):

	2018 Quarters Ended			
Selected Statement of Operations Data:	March 31[1]	June 30	September 30[2]	December 31
Revenue	$102,701	$109,638	$111,806	$120,793
Cost of revenue	36,144	37,386	36,794	42,081
Gross profit	$66,557	$72,252	$75,012	$78,712
Acquired in-process research and development	$—	$—	$30,835	$—
Total operating expenses	$62,512	$62,969	$95,861	$72,043
Income (loss) before income taxes and equity in losses of unconsolidated investee	$4,504	$9,663	$(19,908)	$7,349
(Benefit from) provision for income taxes	$(1,938)	$(4,948)	$1,598	$885
Income (loss) before equity in losses of unconsolidated investee	$6,442	$14,611	$(21,506)	$6,464
Equity in losses of unconsolidated investee	$(951)	$(1,230)	$(920)	$—
Consolidated net income (loss)	$5,491	$13,381	$(22,426)	$6,464
Net loss attributable to non-controlling interest	$—	$—	$(3,496)	$(195)
Net income (loss) attributable to Penumbra, Inc.	$5,491	$13,381	$(18,930)	$6,659
Net income (loss) per share:				
Basic	$0.16	$0.39	$(0.55)	$0.19
Diluted	$0.15	$0.37	$(0.55)	$0.18
Weighted average shares used to compute net (loss) income per share:				
Basic	33,846,142	34,072,223	34,248,484	34,378,415
Diluted	35,917,051	36,116,254	34,248,484	36,150,450

	2017 Quarters Ended			
Selected Statement of Operations Data:	March 31	June 30	September 30[3]	December 31[4]
Revenue	$73,213	$80,589	$83,911	$96,051
Cost of revenue	25,504	29,660	29,134	32,324
Gross profit	$47,709	$50,929	$54,777	$63,727
Acquired in-process research and development	$—	$—	$—	$—
Total operating expenses	$49,755	$52,257	$54,094	$59,871
(Loss) income before income taxes and equity in losses of unconsolidated investee	$(1,751)	$(918)	$1,239	$3,906
Provision for (benefit from) income taxes	$1,355	$482	$456	$(5,904)
(Loss) income before equity in losses of unconsolidated investee	$(3,106)	$(1,400)	$783	$9,810
Equity in losses of unconsolidated investee	$—	$(158)	$(545)	$(727)
Consolidated net (loss) income	$(3,106)	$(1,558)	$238	$9,083
Net loss attributable to non-controlling interest	$—	$—	$—	$—
Net (loss) income attributable to Penumbra, Inc.	$(3,106)	$(1,558)	$238	$9,083
Net (loss) income per share:				
Basic	$(0.10)	$(0.05)	$0.01	$0.27
Diluted	$(0.10)	$(0.05)	$0.01	$0.25
Weighted average shares used to compute net income (loss) per share:				
Basic	31,611,84	B3,219,487	33,446,841	33,606,943

Diluted	31,611,84	3,219,487	35,664,272	35,833,621

(1) In the first quarter of 2018, the Company adopted Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), and its associated amendments. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. The Company applied the five step method outlined in the ASU to all revenue streams and elected to utilize the modified retrospective implementation method. As a result of adoption, the Company recorded a $0.3

million cumulative adjustment to its retained earnings at January 1, 2018. Refer to Note “2. Summary of Significant Accounting Policies” and Note “14. Revenues” for more information.

(2) On August 31, 2018, the Company acquired a controlling interest in MVI which was accounted for as an asset acquisition. In connection with the transaction, the Company recorded a $30.8 million IPR&D charge during the three months ended September 30, 2018 in the consolidated statements of operations related to the acquired technology under development from MVI. Of the total IPR&D charge, $27.4 million was attributable to the net loss of Penumbra, Inc.

(3) Operating expenses for the three months ended September 30, 2017, included a $1.2 million benefit from a net refund of previously paid medical device excise tax.

(4) Income tax expense for the three months ended December 31, 2017, includes $19.8 million of tax benefit related to the release of valuation allowance, offset by $2.4 million of valuation allowance against the Company’s federal research and development tax credits, and $15.4 million of deferred income tax due to the remeasurement of the Company’s DTAs at a 21% corporate income tax rate pursuant to the Tax Reform Act.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that the information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018. Based on this review, our principal executive officer and principal financial officer of the Company have concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2018.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Our management, including our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included in Part II, Item 9A of this Annual Report on Form 10K.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarterly period ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Penumbra, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Penumbra, Inc. and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows as of and for the year ended December 31, 2018 of the Company and our report dated February 26, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

San Francisco, CA
February 26, 2019

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ITEM 9B. OTHER INFORMATION.
None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference to the information set forth in our Definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held in June 2019 ("the 2018 Proxy Statement").

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our principal executive, financial and accounting officers, or persons performing similar functions. Our Code of Ethics is posted under Corporate Governance on the Investor Relations page of our corporate website, www.penumbrainc.com. We intend to make any required disclosures regarding any amendments of our Code of Ethics or waivers granted to any of our directors or executive officers under our Code of Ethics on our website.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the information in the 2018 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item is incorporated by reference to the information in the 2018 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference to the information in the 2018 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference to the information in the 2018 Proxy Statement.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

1. Financial Statements: The financial statements included in “Index to Consolidated Financial Statements” in Part II, Item 8 are filed as part of this Annual Report on Form 10-K
2. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY.

None.

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EXHIBIT INDEX

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit(s)	Filing Date
3.1	Restated Certificate of Incorporation of Penumbra, Inc.	8-K	001-37557	3.3	September 29, 2015
3.2	Amended and Restated Bylaws of Penumbra, Inc.	8-K	001-37557	3.4	September 29, 2015
4.1	Specimen Common Stock Certificate	S-1/A	333-206412	4.1	September 8, 2015
10.1	Lease for facilities at 1351 Harbor Bay Parkway, Alameda, California, dated November 28, 2007 and amended on May 7, 2008 and June 23, 2011	S-1	333-206412	10.1	August 14, 2015
10.2	Lease for facilities at 1411 Harbor Bay Parkway, Alameda, California, dated September 11, 2014	S-1	333-206412	10.2	August 14, 2015
10.3	Lease for facilities at 1321 Harbor Bay Parkway, Alameda, California, dated September 11, 2014	S-1	333-206412	10.3	August 14, 2015
10.4	Lease for facilities at 1301, 1311, 1401 and 1431 Harbor Bay Parkway, Alameda, California, dated December 17, 2015	10-K	001-37557	10.4	March 8, 2016
10.5#	Distribution Agreement between Penumbra, Inc. and Medico's Hirata, dated August 2, 2009, as amended	S-1	333-206412	10.4	August 14, 2015
10.6†	Amended and Restated 2014 Equity Incentive Plan, and forms of Restricted Stock Agreement, Stock Option Agreement and Early Exercise Stock Option Agreement	S-1	333-206412	10.19	August 14, 2015
10.7†	Amended and Restated 2014 Equity Incentive Plan - Restricted Stock Agreement of Penumbra, Inc.	10-Q	001-37557	10.1	November 12, 2015
10.8†	Amended and Restated 2014 Equity Incentive Plan - Stock Option Agreement of Penumbra, Inc.	10-Q	001-37557	10.2	November 12, 2015
10.9†	Amended and Restated 2014 Equity Incentive Plan - Restricted Stock Unit Agreement of Penumbra, Inc.	10-K	001-37557	10.9	March 8, 2016
10.10†	2014 Equity Incentive Plan, and forms of Restricted Stock Agreement, Stock Option Agreement and Early Exercise Stock Option Agreement	S-1	333-206412	10.5	August 14, 2015
10.11†	2011 Equity Incentive Plan, and forms of Restricted Stock Agreement, Stock Grant Agreement, Stock Option Agreement and Early Exercise Stock Option Agreement	S-1	333-206412	10.6	August 14, 2015
10.12†	2005 Stock Plan, and forms of Notice of Grant and Early Exercise Stock Option Agreement	S-1	333-206412	10.7	August 14, 2015
10.13†*	Penumbra, Inc. Amended and Restated 2014 Equity Incentive Plan - Form of Restricted Stock Unit Agreement				
10.14†*	Penumbra, Inc. Amended and Restated 2014 Equity Incentive Plan - Form of Performance-Based Restricted Stock Unit Agreement				
10.15†	Form of Indemnification Agreement by and between Penumbra, Inc. and each of its directors and executive officers	S-1	333-206412	10.9	August 14, 2015
10.16†	Offer Letter with Adam Elsesser	S-1	333-206412	10.10	August 14, 2015

10.17†	Offer Letter with Arani Bose	S-1	333-206412	10.11	August 14, 2015
10.18†	Offer Letter with Sri Kosaraju	S-1	333-206412	10.12	August 14, 2015
10.19†	Offer Letter with Daniel Davis	S-1	333-206412	10.13	August 14, 2015
10.20†	Offer Letter with James Pray	S-1	333-206412	10.14	August 14, 2015
10.21†	Offer Letter with Lynn Rothman	S-1	333-206412	10.15	August 14, 2015
10.22†	Form of Employee Nondisclosure and Assignment Agreement	S-1	333-206412	10.17	August 14, 2015
10.23†	Employee Stock Purchase Plan	S-1/A	333-206412	10.18	August 31, 2015
21.1*	Subsidiaries of the Registrant				

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23.1*	Consent of Deloitte & Touche LLP
24.1*	Power of Attorney (included on signature page)
31.1*	Certification of Principal Executive Officer required under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer required under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer required under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101*	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2018 formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) Consolidated Statements of Operations for the year ended December 31, 2018, 2017 and 2016, (ii) Consolidated Comprehensive Income (Loss) for the year ended December 31, 2018, 2017 and 2016, (iii) Consolidated Statements of Stockholders' Equity (Deficit) for the year ended December 31, 2018, 2017 and 2016, (iv) Consolidated Statements of Cash Flows for the year ended December 31, 2018, 2017 and 2016, and (v) Notes to Consolidated Financial Statements.

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant of confidential treatment.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PENUMBRA, INC.

Date: February 26, 2019

By: /s/ Sri Kosaraju
Sri Kosaraju
Chief Financial Officer and Head of Strategy
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Adam Elsesser and Sri Kosaraju, his attorney-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments in this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connections therewith, with the Securities and Exchange Commission, hereby ratifying and conforming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue of hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Adam Elsesser Adam Elsesser	Chairman, Chief Executive Officer and President (principal executive officer)	February 26, 2019
/s/ Sri Kosaraju Sri Kosaraju	Chief Financial Officer and Head of Strategy (principal financial officer and principal accounting officer)	February 26, 2019
/s/ Arani Bose Arani Bose	Chief Innovator and Director	February 26, 2019
/s/ Don Kassing Don Kassing	Director	February 26, 2019
/s/ Harpreet Grewal Harpreet Grewal	Director	February 26, 2019
/s/ Thomas C. Wilder Thomas C. Wilder	Director	February 26, 2019
/s/ Bridget O'Rourke Bridget O'Rourke	Director	February 26, 2019
/s/ Janet Leeds Janet Leeds	Director	February 26, 2019