Penumbra Inc
Form 10-K
March 08, 2016

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, 2015
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 (State or Other Jurisdiction of Incorporation or Organization)	05-0605598 (I.R.S. Employer Identification No.)
One Penumbra Place 1351 Harbor Bay Parkway Alameda, CA (Address of Principal Executive Offices) (510) 748-3200 (Registrant's telephone number, including area code)	94502 (Zip 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: o No: x
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 and posted on its corporate Web site, if any, 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. Yes: o No: o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x (Do not check if a smaller reporting Company)	Smaller reporting company	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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore cannot calculate the aggregate market value of its voting and nonvoting common equity held by nonaffiliates as of such date.

As of January 31, 2016, the registrant had 29,978,983 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 2016 annual meeting of stockholders, which is to be filed not more than 120 days after the registrants fiscal year ended December 31, 2015, 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 interventional therapies company that designs, develops, manufactures and markets innovative medical devices. We have a broad portfolio of products that addresses challenging medical conditions and significant clinical needs across two major markets, neuro and peripheral vascular. The conditions that our products address include, among others, ischemic stroke, hemorrhagic stroke and various peripheral vascular conditions that can be treated through thrombectomy and embolization procedures.

We are an established company focused on the neuro market, and we recently expanded our business to include the peripheral vascular market. We focus on developing, manufacturing and marketing products for use by specialist physicians, including interventional neuroradiologists, neurosurgeons, interventional neurologists, interventional radiologists and vascular surgeons. We design our products to provide these specialist physicians with a means to drive improved clinical outcomes through faster and safer procedures.

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 capital-efficient manner.

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. Some of our key accomplishments include:

- launching our first product, for neurovascular access, in the U. S. in 2007;
- establishing our direct neuro salesforce in the U. S. and Europe in 2008;
- launching the first 510(k)-cleared, aspiration-based product for the treatment of ischemic stroke patients in 2008, and launching four subsequent generations of that product;
- launching our first neurovascular coil for the treatment of brain aneurysms in 2011;
- launching our first peripheral vascular product in 2013; and
- establishing our direct peripheral vascular salesforce in the U. S. and Europe in 2014.

We sell our products to hospitals primarily through our direct sales organization in the U. S., most of Europe, Canada and Australia, as well as through distributors in select international markets. In 2015, we generated revenue of $186.1 million, which represents a 48.3% increase over 2014, and $4.2 million in operating income as compared to an operating income of $3.0 million in 2014. For the year ended December 31, 2014, we generated revenue of $125.5 million, which represented a 41.3% increase over 2013, and $3.0 million in operating income as compared to an operating loss of $1.1 million in 2013.

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Our Products

Since our founding in 2004, we have invested in expanding our product development and marketing capabilities. These investments have included engineering and materials science capabilities, pre-clinical and bench-testing infrastructure and in-house clinical and regulatory infrastructure. Our fully-integrated organization has enabled us to launch 16 product brands for access, thrombectomy and embolization since 2007 to service our two target end markets. The following table summarizes our product offerings in each of our target end markets:

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OUR NEURO PRODUCTS

Neurovascular Access

Accessing the brain through the tortuous neurovasculature has been a substantial challenge for physicians treating vascular disorders in the brain. Companies developing products for neurovascular applications have 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.

Our portfolio of neurovascular access products includes our Neuron Access System catheters, BENCHMARK Intracranial Access System catheters and a variety of microcatheters.

Neuron Access System

We recognized the challenges posed by existing access technologies and focused our initial efforts on developing a guide catheter system designed specifically for neurointerventional procedures. Our Neuron delivery catheter is a variable stiffness guide catheter with increased support in the aortic arch, which enables trackability to access the intracranial vasculature. The design of Neuron enables physicians to position the catheter much higher in the anatomy than conventional guide catheters.

We believe the Neuron family of guide catheters and the Penumbra distal delivery catheters that we subsequently introduced have enabled many neuro-endovascular procedures that previously had not been possible in the tortuous anatomy of the neurovasculature. We have continued our development and currently offer a wide range of catheters that enable delivery of the different therapeutic catheters that are required for ischemic and hemorrhagic stroke interventions. Our Neuron products include the following:

- The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. The system is a two-catheter system comprised of the Neuron Delivery Catheter and the Select Catheter.
- The Neuron Delivery Catheter is a variable stiffness, large lumen catheter that combines proximal arch support with a microcatheter-like distal segment that is designed to access the intracranial anatomy. The Neuron can be used individually with a 0.038 inch guidewire, or together with the Neuron Select Catheter, to access the desired location.
- The Select Catheter is a single lumen, braid-reinforced, torquable catheter with a radiopaque distal end and a hub on the proximal end. The Select Catheter enables primary access with the Neuron Delivery Catheters, obviating the need for an extra guide catheter.
- The Neuron MAX System is an additional configuration to the currently available Neuron Intracranial Access System. The Neuron MAX System is a long sheath catheter with a flexible distal tip for neurovascular use and provides a larger lumen to enable a wide range of device compatibility in neurovascular procedures.

BENCHMARK Intracranial Access System

Advances in our catheter technology, driven largely by our advances in ischemic stroke therapy, have enabled us to further develop our intracranial access category of products. Our latest development in this category is the BENCHMARK catheter, which features additional improvements in ease-of-use, trackability, and aortic arch support that we believe will further enhance our position in the neurovascular access market.

The BENCHMARK catheter technology achieves these improvements by combining our advanced tracking technology with the original Neuron intracranial access concept. In addition to improved proximal support in the arch through multi-geometry metal reinforcement, the distal tip is softer and more trackable, while maintaining complete 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 reduces the number of devices needed per procedure and shortens procedure times.

Ischemic Stroke

Penumbra System

We developed our aspiration-based Penumbra System family of products to enable specialist physicians to revascularize blood vessels that are blocked by clots in the intracranial vasculature. We launched our first Penumbra System product in 2008 in the U. S.. We believe ACE, launched in June 2013, and ACE 64, launched in May 2015, represent significant advancements over prior generations of the Penumbra System.

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Overview of the Penumbra System

Our Penumbra System family of products is comprised of several principal components, which include:

- Penumbra Reperfusion Catheters are the cornerstone of the Penumbra System and are manufactured using a variety of proprietary processes and materials science innovations. We have launched five successive generations of Reperfusion Catheters since 2008.
- The latest generation of our Reperfusion Catheters, the ACE family of catheters, represents our most powerful and trackable Reperfusion Catheters launched to date. Its design enables specialist physicians to track these large bore aspiration catheters to the distal locations of occluded vessels. Once at the site of the occlusion, ACE provides significantly greater aspiration power than our prior Reperfusion Catheters, which we believe contributes to improved clinical outcomes and reduced procedure times.
- ACE 64, our latest generation of ACE catheter, is designed to offer enhanced aspiration power relative to prior generations of the product, while maintaining trackability. ACE 64 launched in the U. S. in late May 2015.
- Penumbra Separators are a component of the earlier generations of the Penumbra System and 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, which resulted in frequent obstruction of the catheter. With the launch of our larger diameter ACE, Separators are less frequently used by physicians.
- 3D is a stent retriever component of the Penumbra System that allows a physician to combine direct aspiration with stent retriever technology. 3D is being evaluated in a clinical study pursuant to an Investigational Device Exemption (IDE) to obtain clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). With 198 of the anticipated 230 patients enrolled, the Data Safety Monitoring Board for this study recently temporarily suspended further enrollment in order to assess the data. The Board indicated that the suspension was not due to safety issues.
- Penumbra Aspiration Pumps are attached to our Reperfusion Catheters and provide the aspirating suction force. Our second generation MAX Aspiration Pump features increased aspiration capabilities and an improved, easier to use design. We have standardized the MAX Aspiration Pump to work with all generations of our Reperfusion Catheters.

Evolution of Penumbra System’s Reperfusion Catheters

The Penumbra System Reperfusion Catheters are the foundation of the Penumbra System. The principal generations of our Reperfusion Catheters include the original Penumbra System, Penumbra System MAX, Penumbra System ACE and Penumbra System ACE 64. We have introduced five successive generations of these catheters since early 2008. Each subsequent generation of our Reperfusion Catheters has incorporated significant performance enhancements relative to prior generations with regard to trackability and aspiration power.

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The Generations of the Penumbra System

The Original Penumbra System

Our original Penumbra System was CE-marked in September 2006 and 510(k) cleared by the U.S. Food and Drug Administration (FDA) in December 2007. The Penumbra System is intended for use in the revascularization of patients with ischemic stroke within eight hours of symptom onset.

Our original Penumbra System was evaluated in the Penumbra Pivotal study, a 125 patient clinical study to assess the safety and effectiveness of the Penumbra System in the revascularization of patients presenting with ischemic stroke. This study was sponsored by Penumbra to support and obtain regulatory clearance for the original Penumbra System. The Penumbra Pivotal study demonstrated an 81.6% success rate in achieving successful revascularization. The study was completed in 2007 and the results were published in the journal Stroke in 2009.

We had commissioned and subsequently evaluated the Penumbra System in our THERAPY study, a clinical study comparing the clinical outcomes in the medical management of stroke patients with IV recombinant tPA (rtPA) to stroke patients treated with a combination of IV rtPA and the Penumbra System. The THERAPY study was commenced in March 2012, and was designed to enroll up to 692 patients, but was stopped early in October 2014, because the positive results of the MR CLEAN study made it unethical to continue to treat the control group in the THERAPY study with medical management rather than with endovascular treatment. The MR CLEAN study demonstrated the superiority of endovascular treatment of stroke over medical management. As a result, the steering committee for THERAPY recommended stopping enrollment for the trial. The THERAPY study results, after the randomization of 108 patients, were presented in April 2015 at the European Stroke Organization Conference and the manuscript is being prepared for submission to a peer-reviewed journal. Despite the early termination of the study, the pre-specified per protocol analysis demonstrated a significant benefit of combined treatment with IV rtPA and the Penumbra System over IV rtPA alone.

Penumbra System MAX

The Penumbra System MAX applies our advanced tracking technology and improved aspiration power to the Penumbra System’s aspiration platform. Launched in 2011, the 3MAX and 4MAX Systems feature MAX Tracking Technology that allows access over a solo guidewire for an even faster, easier procedure than with our original Penumbra System. The proximal shaft of these specialized catheters incorporates tapering, larger diameters, enabling increased aspiration power. In August 2012, we launched the 5MAX, which added our MAX Tracking Technology to an even larger dimension Reperfusion Catheter.

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ACE

Almost a decade of research and product development culminated in the introduction of our first ACE Reperfusion Catheter in July 2013. ACE features a unique tapered design, large lumen diameter and other developments that result in significantly greater aspiration power and improved trackability compared to our earlier original Penumbra System and Penumbra MAX products.

Given its improved aspiration power and larger lumen size, our ACE Reperfusion Catheter can enable the extraction of a fibrous thrombus without fragmentation and often in one solid piece. This leaves the longitudinal fibrin strands in the clot intact, allowing the thrombus to retain its integrity. We believe this is evidenced in our post-launch clinical experience, in which clinicians have seen high rates of TICI 3 revascularization, representing complete recanalization of the affected area, using our ACE catheters.

Our ACE 64 Reperfusion Catheter was launched in the U. S. in May 2015. It is built on our ACE platform and offers an increased lumen diameter, which leads to further increased aspiration power and which we believe will aid in the removal of clot from the neurovasculature.

Neurovascular Embolization

Given the minimal product differentiation among the existing coils on the market, we concluded that to initially penetrate this market successfully we would have to develop a coil that was materially easier to deliver, and provided a procedural economic advantage. We also identified a segment of aneurysms that traditional neurovascular coils could not effectively treat on a cost effective basis. These included larger aneurysms and other larger, more complex lesions. We estimate that these aneurysms and lesions currently represent less than 10% of the addressable aneurysms.

The Penumbra Coil 400

We developed our Penumbra Coil 400 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. Our coil system is composed of a platinum embolization coil complemented by a nitinol inner structure and stretch resistant nitinol wire. It is attached to a composite delivery pusher with a radiopaque positioning marker. The Penumbra Detachment Handle offers instant mechanical detachment of the coil and can be controlled by the physician in the sterile field.

We received 510(k) clearance for the Penumbra Coil 400 in 2011. The Penumbra Coil system is FDA cleared for endovascular embolization of intracranial aneurysms and other neurovascular abnormalities.

Review of Penumbra Coil 400 Clinical Performance

Given the size and handling of the Penumbra Coil 400, it is able to achieve higher packing density with fewer coils compared to competitive coiling systems. These findings have been confirmed in numerous physician sponsored post-marketing studies. Collectively, the clinical studies have shown that use of the Penumbra Coil 400 resulted in:

- less retreatments or worsening occlusions;
- larger aneurysm treatment capabilities;
- higher packing density; and
- fewer coils per aneurysm.

Penumbra SMART Coil

Leveraging our initial experience treating larger aneurysms and more complex lesions with the Penumbra Coil 400, we turned our efforts to developing a standard sized coil to compete in the traditional, smaller neurovascular coil market. While the market has seen significant growth over the last 15 years, there has been very little innovation in the last several years with regard to coil design, material science and performance. As a result, neurovascular coils built on the traditional, smaller-coil platform offer very little differentiation in terms of materials, ease-of-use and trackability.

In light of these dynamics, we focused our development efforts on a coil that would improve ease of delivery, or “feel” of the coil compared to the leading established coils. In order to accomplish this, our engineering team developed a highly sophisticated coil that dramatically changes its softness profile within the span of a single individual coil. This progressive softness feature enables physicians to pack the coil into a delicate lesion and mitigate catheter kick-back at the end of delivery, which can preclude the successful complete embolization of the lesion.

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The Penumbra SMART Coil is 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. Alternative products available to physicians in this market are offered in single levels of softness - standard, soft or extra soft. The three principal levels of softness that competitors offer are derived from using smaller platinum filaments to increase the level of softness. However, this methodology does not allow for changes to the softness level within an individual coil. The design of the 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 the Penumbra SMART Coil to become progressively softer within the span of an individual coil.

We introduced our SMART Coil in the fourth quarter of 2015. We believe that it will provide us with another important opportunity to offer specialist physicians a broader suite of products to address their neurovascular coiling needs.

Neurosurgical Tools

The Apollo System

We received 510(k) clearance from the FDA for our first neurosurgical product, the Apollo System, in 2014. The Apollo system leverages our expertise in thrombectomy and access to offer a minimally invasive approach to surgical removal of fluid and tissue from the ventricles in the brain.

The Apollo system is comprised of two primary components:

- the Apollo wand that is inserted into the brain through an endoscope, which, in turn, is inserted through a small burr hole into the skull; and
- a reusable hardware device that delivers vacuum, irrigation and vibrational energy along the disposable wand to the site of the hemorrhage.

OUR PERIPHERAL VASCULAR PRODUCTS

After initially focusing our business on our neuro products, we identified the peripheral vascular market as an ideal opportunity to leverage our neuro experience and our core expertise in thrombectomy, embolization and access technologies to develop new products that could address significant clinical needs cost effectively.

The peripheral vasculature suffers from disorders that are very similar to those experienced in the neurovasculature that our products already successfully address. For example, weakening of the vascular walls can result in aneurysms, and blockages can form as the result of embolism or advanced atherosclerosis. 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 peripheral vasculature also presents unique challenges that do not apply to interventional efforts in the brain. 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.

In 2012, we began investing further in research and development to evaluate and identify potential solutions to address significant clinical needs in the peripheral vasculature. Our products for the treatment of peripheral vascular disease focus on:

- peripheral vascular embolization;
- vessel occlusion; and
- peripheral vascular thrombectomy.

Peripheral Embolization

Ruby Coil System

After completing research and development focusing on the specific requirements of the peripheral embolization market, we launched our Ruby Coil System for use in the peripheral vascular market in 2013. The Ruby Coil System consists of detachable coils that are specifically designed for peripheral applications. The 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. Compared to pushable coils, this minimizes costly complications

like embolizing unintended vessels.

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The Ruby Coil System is used in a variety of clinical applications, including:

- 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.

We believe our Ruby Coil System offers specialist physicians a differentiated, cost-effective solution in the treatment of peripheral embolization patients.

Lantern

After entering the peripheral embolization market, we developed the Lantern Microcatheter to address unmet clinical needs. We received 510(k) clearance for the Lantern Microcatheter in December 2015. The Lantern Microcatheter is offered in a variety of lengths and tip shapes relevant to peripheral vascular procedures. The distal segment of Lantern is visual under fluoroscopy to aid in the navigation and visualization of the microcatheter during procedures.

POD (Penumbra Occlusion Device)

We developed POD, our peripheral vascular occlusion device, to address a specific need in the peripheral embolization market to rapidly and precisely occlude a target vessel. Current options for vessel occlusion in the periphery are limited, either requiring multiple devices or difficult to deliver vascular plugs. Microcatheter deliverable devices, such as coils, are not ideally suited for vessel embolization due to their tendency to migrate with antegrade flow and generally require the deployment of several devices to achieve occlusion. Vascular plug technology for larger peripheral vessels requires access with large diagnostic catheters or even larger bore sheaths. Additionally, these devices often require the placement of adjunctive devices, such as coils, to achieve complete occlusion. 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. We received 510(k) clearance for POD in July 2014. Unlike conventional vascular plugs, our POD technology enables the occlusive device to be delivered through a microcatheter. Additionally, a single POD can occlude a range of vessel diameters, reducing the need for sophisticated measurement prior to embolization.

Our POD technology leverages the key features of a dedicated vessel embolization device to improve ease-of-use. These include:

- microcatheter deliverability;
- instant detachment;
- immediate and precise anchoring;
- a single device to treat a range of vessel diameters; and
- dense occlusion in a short segment.

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. Once POD is deployed, it can be detached instantly with the sterile detachment handle.

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POD Packing Coil

We introduced the POD Packing Coil in January 2016 as 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.

Peripheral Thrombectomy

Indigo System

Our Indigo System, which we launched in 2014, was designed for continuous aspiration mechanical thrombectomy (CAT), leveraging the success of the Penumbra System in ischemic stroke. The Indigo System is designed to remove clots in the peripheral arteries and veins.

Our Indigo System family of products and accessories is an easy to use thrombectomy system that is powerful, highly trackable, and suited to a wide range of clot morphology. The principal components include:

- Continuous Aspiration Mechanical Thrombectomy Catheters are the foundation of the system and are ideally suited to reach anatomy below the knee. Much like our MAX and ACE catheters, the CAT catheters are robust, durable, trackable and suited for the peripheral anatomy. The initial launch of the Indigo System included our CAT5 catheter and the device made for more distal access, CAT3, which is able to reach the distal peripheral vessels of the upper and lower extremities. On May 26, 2015, we received FDA clearance for CAT6 and CAT8, two larger sizes of the Indigo System, as well as to market the Indigo System for use in both the peripheral arterial and venous systems.
- Indigo Separator enables the peripheral interventionalist to remove a difficult to aspirate clot from the CAT catheter. In the peripheral vessels, clots often form in long segments, and are more resistant to traditional aspiration techniques. The Indigo System with the Separator enables a wide range of clot morphology to be removed from the body. While conclusions should not be drawn from initial results and further results may prove to be worse or inconclusive, we have demonstrated in clinical settings that the Indigo System with the Separator can remove clots that were resistant to hours of revascularization attempts with other technologies and thrombolytic agents.
- Penumbra Aspiration Pump is the power source that provides the aspirating suction force to remove waste, such as blood and clots.

Research and Development

We direct our research efforts towards the development of clinical therapies that expand the therapeutic alternatives available to specialist physicians and improve upon our existing product offerings. Our research and development team has a track record of product innovation and significant product improvements. Since inception, we have introduced 16 products brands in either the U. S., international markets, or both. Our research and development expenses totaled $18.0 million, $15.6 million and $14.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

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 both significant experience in the development of medical devices as well as engineers directly from undergraduate and graduate programs that have become immediately productive within our development process. We have a pipeline of products in various stages of development that are expected to provide additional commercial opportunities. All of our research and development efforts are based at our campus in Alameda, California.

Manufacturing

We currently maintain one manufacturing facility at our campus in Alameda, California, which, together with our research and development space, totals 180,000 square feet. The manufacturing facilities run two eight-hour shifts per weekday. In addition, in December 2015, we signed a lease for an additional 99,568 square feet of space at our campus in Alameda, giving us capacity to increase production, and allowing us to expand adjacent to our current facilities. We currently produce substantially all of our products in-house.

Our rigorous quality control management programs have earned us a number of quality-related manufacturing designations. Our manufacturing facilities are EN ISO 13485 compliant with ISO 13485-2003 certification achieved in 2005. In 2007, we achieved compliance with MDD standards, allowing our products to be CE marked. We use annual internal audits, combined with external audits by regulatory agencies to help 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.

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Sales and Marketing

We have dedicated substantial resources to establish a direct sales capability in the U. S., most of Europe, Canada and Australia, which we have complemented with distributors in Japan and certain other international markets. We have regulatory clearance to sell our neurovascular access, ischemic stroke, neurovascular embolization, peripheral embolization and peripheral thrombectomy products in two of our three major markets, the U. S. and Europe, except that 3D has been cleared in Europe but not the U. S. In our third major market, Japan, we have regulatory clearance to sell our ischemic stroke, neurovascular embolization and peripheral embolization products. The only access product that has received regulatory clearance in Japan is PXSLIM. 3D, Ruby Coil, ACE 64 and Indigo System have not received regulatory clearance in Japan. Our Penumbra Coil 400 products are also used for peripheral embolization in Japan, and have received regulatory clearance for that use in that market. Liberty Stent has not yet received regulatory clearance anywhere. We believe our global presence enables us to capitalize on the markets for neuro and peripheral vascular devices that exist outside of the U. S.

We currently sell our products to hospitals in the U. S. through our dedicated salesforce in two target end markets, neuro and peripheral 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 neurovascular and peripheral 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: