InspireMD, Inc.
Form 10-K
February 19, 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

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

COMMISSION FILE NUMBER: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification Number)

4 Menorat Hamaor St.
Tel Aviv, Israel
(Address of principal executive offices)

6744832
(Zip Code)

Registrant's telephone number, including area code: **(888) 776-6804**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value	NYSE American

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [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 [ ] 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 [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 [X] No [ ]

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 [ ] Accelerated filer [ ]

Non-accelerated filer [X] Smaller reporting company [X]

Emerging growth company [ ]

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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes [ ] No [X]

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2018, based on the price at which the common equity was last sold on the NYSE American on such date, was $1,603,155. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

Indicate the number of shares outstanding of each of the registrant’s classes of common stock as of the latest practicable date.

Class	**Outstanding at February 18, 2019**
Common Stock, $0.0001 par value	41,888,895

Documents incorporated by reference:

None

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PART I

In this Annual Report on Form 10-K, unless the context requires otherwise, the terms "we," "our," "us," or "the Company" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries, including InspireMD Ltd., taken as a whole.

Item 1. Business.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately $1.0 billion in 2017. (source: *Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets*).

In April 2017, we had a pre-investigational device exemption ("IDE") submission meeting with the U.S. Food and Drug Administration regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. The FDA agreed to our pre-clinical test plan and clinical trial design. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States. We intend to make an IDE submission seeking

approval to conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever. In addition, such additional financings may be costly or difficult to complete. Even if we receive sufficient proceeds from future financings, there is no assurance that we will be able to timely apply for CE mark approval following our receipt of such proceeds. We believe these improvements and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

Our MGuard™ Prime™ Embolic Protection System ("MGuard Prime EPS") is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES™. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES™.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to seal aneurysms in the brain.

Presently, none of our products may be sold or marketed in the United States.

In 2017, we decided to shift our commercial strategy to focus on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Pursuant to our new strategy, we completed our transition away from a single distributor covering 18 European countries to a direct distribution model intended to broaden our sales efforts to key clinical specialties. All territories previously covered by our former European distributor were transferred to local distributors by June 2017. We also have begun to participate in international trade shows and industry conferences in an attempt to gain market exposure and brand recognition**.**

We were organized in the State of Delaware on February 29, 2008.

Recent Developments

NYSE American Notification

On August 17, 2017, we received a notice from NYSE American indicating that we do not meet the continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the "Company Guide"). Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of June 30, 2017, and net losses in our five most recent fiscal years ended December 31, 2016. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 19, 2017, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by February 19, 2019. We are subject to periodic review by the NYSE American staff during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

On November 22, 2017, we received an additional letter from the NYSE American indicating that we are not in compliance with the stockholders' equity and net income continued listing standards set forth in Section 1003(a)(ii) of the Company Guide because we reported stockholders' equity of less than $4 million as of September 30, 2017. We have until February 17, 2019, to regain compliance with the continued listing requirements.

On January 16, 2018, we received notification from the NYSE American that we are not in compliance with certain NYSE American continued listing standards. The deficiency letter states that our shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 16, 2018.

Effective as of 5:00 p.m. Eastern Time on February 7, 2018, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-35 reverse stock split of our outstanding shares of common stock.

On July 16, 2018, we received notification from the NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide. We remain below compliance with Sections 1003(a)(ii) and (iii) of the Company Guide.

However, on January 7, 2019, we again received notification from the NYSE American that we are not in compliance with the NYSE American continued listing standards because our shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 7, 2019.

Our Industry

Carotid

Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. Carotid artery disease, also called carotid artery stenosis, is a type of atherosclerosis (hardening of the arteries) that is one of the major risk factors for ischemic stroke. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply to the brain. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke. According to the World Heart Federation (*http://www.world-heart-federation.org/cardiovascular-health/stroke/*, last visited on Mar. 11, 2016), every year, 15 million people worldwide suffer a stroke, and nearly six million die and another five million are left permanently disabled. According to the same source, stroke is the second leading cause of disability, after dementia.

In 2017, 2.2 million people were diagnosed with carotid artery disease, of which, approximately 600,000 patients had high grade carotid stenosis requiring intervention for carotid artery disease *(2017 Health Research International Market Report*). At an average price of $1,650 per stent, the addressable market is more than $1 billion. Carotid artery stenting is a minimally invasive treatment option for carotid artery disease and an alternative to carotid endarterectomy, where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and carotid embolic prevention system protect against plaque and debris traveling downstream, blocking off the vessel and disrupting blood flow. We believe that the use of a stent with an embolic protection system should increase the number of patients being treated since it would

avoid the need for complex surgery.

Coronary

Physicians and patients may select from a variety of treatments to address coronary artery disease, including pharmaceutical therapy, balloon angioplasty, stenting with bare metal or drug-eluting stents, and coronary artery bypass graft procedures, with the selection often depending upon the stage of the disease.

The global market value of coronary products is estimated at $5.9 billion, of which $4.2 billion is for stable angina and $1.7 billion is for acute myocardial infarctions according to Health Research International (June 2011). According to the 2014 MEDTECH OUTLOOK produced in December 2013 by BMO Capital Markets ("MEDTECH OUTLOOK"), revenues from the global coronary stent market are predicted to slightly decline, although in volume of stents the market is predicted to continue to grow. We believe the growth in volume is due to the appeal for less invasive percutaneous coronary intervention ("PCI") procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Neurovascular

The neurovascular market focuses on catheter-delivered products used to treat strokes that already happened or unruptured brain aneurysms that could lead to strokes. In the latter case, coils are wound into blood vessel bulges to block blood flow entering the aneurysms to prevent the aneurysms from rupturing. Endovascular treatment of arterial aneurysm has evolved substantially over the past two decades, transitioning from an investigational therapy into routine clinical practice and ultimately emerging as the treatment of choice for many lesions *(source: Medtech Ventures 2009, Aneurysm Flow Modulating Device Market).* We believe that the market for aneurysm flow modulating devices is still in the embryonic stage with windows of opportunities for early entrance.

The current global market for the aneurysm flow modulating devices is estimated at $550 million, and the current market value of the flow diversion market segment is estimated to be $125 million. The neurovascular market includes over-the-wire, flow-guided microcatheters, guiding catheters, coil and liquid embolics, neurovascular stents and flow diversion stents. According to iData Research, the market is expected to be driven by the conversion from surgical procedures to endovascular techniques in the treatment of aneurysms and arteriovenous malformations.

Peripheral

Peripheral vascular diseases ("PVD") are caused by the formation of atherosclerotic plaques in arteries, which carry blood to organs, limbs and head. It is also known as peripheral artery occlusive disease or peripheral artery disease. It comprises diseases pertaining to both peripheral veins and peripheral arteries, affecting the peripheral and cardiac circulation in the body. PVD includes diseases outside of the heart and brain, but most times refers to the leg and foot.

The global market value of PVDs is estimated at $1.6 billion by 2017 (*source: Global Data 2011*). The overall peripheral vascular devices market consists of nine different product segments: peripheral vascular stents, chronic total occlusion devices, peripheral transluminal angioplasty balloon catheters, atherectomy devices, percutaneous transluminal angioplasty guidewires, aortic stents, embolic protection devices, synthetic surgical grafts and inferior vena cava filters *(source: Grand View Research 2014).* Treatment modalities and methods have considerably improved during the last several years, and this trend is expected to continue (*source: Global Data 2011*). Stents and balloons hold the majority of the share in the peripheral vascular devices market. Peripheral stents are more often used in combination with balloon angioplasty to open the veins, so that blood can flow through the blocked veins in the body.

The growing prevalence of PVD is expected to cause increased demand for treatment options. The expansion of the elderly population is contributing to increasing incidence rates of PVD. The percentage of the global population above the age of 50 is expected to reach 17% by 2030. As the risk of developing PVD increases with age, a growing elderly population translates into a growing incidence of PVD (*source: Global Data 2011*). The growing global geriatric population base also triggers increasing demand for minimally invasive endovascular procedures on account of their shorter recovery time, lesser scaring and lesser chances of post-surgery infections. In addition, a growing prevalence of disease-causing lifestyle factors and eating habits such as high consumption of alcohol and tobacco products is expected to boost peripheral vascular devices market demand by triggering the incidence rates of cardiac arrest, blood clotting and other vascular diseases *(source: Grand View Research 2014).*

Our Products

Below is a summary of our current products and products under development, and their intended applications.

MicroNet

MicroNet is our proprietary circular knitted mesh which wraps around a stent to protect patients from plaque debris flowing downstream upon deployment. MicroNet is made of a single fiber from a biocompatible polymer widely used in medical implantations. The size, or aperture, of the current MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus.

CGuard – Carotid Applications

Our CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) in a single device for use in carotid artery applications. MicroNet is placed over and attached to an open cell nitinol metal stent platform which is designed to trap debris and emboli that can dislodge from the diseased carotid artery and potentially travel to the brain and cause a stroke. This danger is one of the greatest limitations of carotid artery stenting with conventional carotid stents and stenting methods. The CGuard EPS technology is a highly flexible stent system that conforms to the carotid anatomy.

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical endarterectomy, given the superior embolic protection characteristics provided by the MicroNet. We believe the MicroNet will provide acute embolic protection at the time

of the procedure, but more importantly, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur up to 48 hours post-procedure. It is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain. Schofer, et al. ("Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

Our CGuard EPS with over-the-wire delivery system received CE mark approval in the European Union in March 2013. In October 2014, we initiated a limited market release of CGuard EPS with over-the-wire delivery system for use in carotid artery applications in Germany, Poland and Italy.

In September 2014, we reported the results of the CGuard CARENET trial at the Transcatheter Cardiovascular Therapeutics ("TCT") conference in Washington D.C. In the CARENET trial, the CGuard EPS system demonstrated better results over historical data using conventional commercially available carotid stents. In the third quarter of 2015 the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve-month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

In the first quarter of 2015, we introduced CGuard RX, the new rapid exchange delivery system for CGuard EPS. The rapid exchange delivery system has a guidewire that passes through the delivery system, running through the guiding catheter. It has one port, and thus, can be operated by one operator, while an over-the-wire-delivery system has two lumens and ports and requires two operators to perform the procedure. Our rapid exchange delivery system received CE mark approval in January 2015. We launched our CGuard EPS in Europe with the rapid exchange delivery system in multiple medical specialties that perform carotid artery stenting. These customers include interventional cardiologists, vascular surgeons, interventional neuroradiologists and interventional radiologists.

In September 2015, we announced full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including [India.

In April 2017, we had a pre-IDE submission meeting with the U.S. Food and Drug Administration regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. The FDA agreed to our pre-clinical test plan and clinical trial design. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever. In addition, such additional financings may be costly or difficult to complete. Even if we receive sufficient proceeds from future financings, there is no assurance that we will be able to timely apply for CE mark approval following our receipt of such proceeds. We believe these improvements and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

MGuard Products– Coronary Applications

Bare-Metal Stent MGuard Product. Our MGuard Prime EPS coronary product is comprised of MicroNet wrapped around a cobalt-chromium based bare-metal stent. In comparison to a conventional bare-metal stent, we believe our MGuard Prime EPS coronary product with MicroNet mesh provides protection from dangerous embolic showers in patients experiencing ST-segment elevation myocardial infarction, the most severe form of a heart attack, referred to as STEMI. Standard stents were not engineered for heart attack patients. Rather, they were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient. In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages in a significant portion of heart attack patients. Our MGuard Prime EPS is integrated with a precisely engineered micro net mesh that is designed to prevent the unstable arterial plaque and thrombus that caused the heart attack blockage from breaking off.

NGuard — Neurovascular Applications

We began developing a neurovascular flow diverter, which we refer to as NGuard, which is an endovascular device that diverts blood flow away from cerebral aneurysms and ultimately seals the aneurysms. Flow diversion is a growing market segment within the neurovascular medical device field. Current commercial flow diverters are highly flexible dense metal mesh tubes that go across most types of cerebral aneurysms and divert the blood flow away from the aneurysm with the desired end result of sealing the aneurysm. The challenges with the current flow diverters are that they (i) are difficult to place given the high metal content in the device, which makes it more difficult to move the device through the delivery system due to resistance from the metal, and to subsequently accurately place it, (ii) need to be accurately placed to avoid crossing and blocking other cerebral vessels, which could cause additional damage by cutting off blood flow to sections of the brain, (iii) require chronic use of anti-thrombotic medications due to the amount of metal in the cerebral vasculature, which could cause thrombotic complications, and (iv) do not allow a physician to re-access the aneurysm if the aneurysm does not seal, in which event the aneurysm may need to be treated with another therapy such as aneurysm coils, due to the tight metal mesh that will not allow other devices to pass through the flow diverter.

Our flow diverter prototype will include our MicroNet that has been employed in CGuard EPS and MGuard Prime EPS. MicroNet has already demonstrated the ability to effectively seal aneurysms in human coronary arteries using the MGuard Prime EPS and aneurysms in the carotid arteries using CGuard EPS in human clinical situations without the need for additional devices or procedures (coils or a second stent) (*source: Journal of Medical Case Reports http://www.jmedicalcasereports.com/content/4/1/238*). For our flow diverter, we plan to utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We believe our flow diverter could be more accurately delivered due to a lower metal content scaffold than current commercial flow diverters. Lower metal content in our flow diverter may reduce the need for long-term anticoagulation; the open cell metal scaffold combined with the MicroNet may allow passage of other devices through the MicroNet mesh without compromising the MicroNet, thus allowing a physician to reaccess the aneurysm, if needed; and our flow diverter should be capable of being delivered through a state-of-the-art microcatheter for accurate placement without constant repositioning. We have tested early flow diverter prototypes in initial pre-clinical testing in both simulated aneurysm bench models using various MicroNet configurations with varying aperture sizes, as well as in standard in vivo pre-clinical models, in which we observed aneurysm sealing and also wide open side branch vessels across which the device was placed. We have suspended all further development activity of NGuard until we obtain sufficient funding for such purpose.

PVGuard — Peripheral Vascular Applications

We intend to develop our MicroNet mesh sleeve and a self-expandable stent for use in peripheral vascular applications, to which we refer to as PVGuard. PVDs are usually characterized by the accumulation of plaque in arteries in the legs. This accumulation can lead to the need for amputation or even death, when untreated. PVD is treated either by trying to clear the artery of the blockage, or by implanting a stent in the affected area to push the blockage out of the way of normal blood flow.

As in carotid procedures, peripheral procedures are characterized by the necessity of controlling embolic showers both during and post-procedure. Controlling embolic showers is so important in these indications that physicians often use fully covered stents, at the risk of blocking branching vessels, to ensure that emboli do not fall into the bloodstream and move to the brain. We believe that our MicroNet design will provide substantial advantages over existing therapies in treating peripheral artery stenosis.

However, as we plan to focus our resources on the further expansion of our sales and marketing activities for CGuard EPS and MGuard Prime EPS and, provided that we have sufficient resources, the development of CGuard EPS with a smaller delivery catheter (5 French gauge) and its submission for CE mark approval, we do not intend to pursue the development of PVGuard in the near future.

Completed Clinical Trials for CGuard EPS

CARENET

The CARENET trial was the first multi-center study of CGuard EPS following the receipt of CE mark of this device in March 2013. The CARENET trial was designed to evaluate feasibility and safety of CGuard EPS in treatment of carotid lesions in consecutive patients suitable for coronary artery stenting ("CAS") in a multi-operator, real-life setting. The acute, 30 day, magnetic resonance imaging ("MRI"), ultrasound and six month clinical event results were presented at the LINC conference in Leipzig, Germany in February, 2015. In the third quarter of 2015, the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

MACCE (myocardial infarction ("MI"), stroke or death) rate was 0.0% at 30 days. At six months, there was one death, which was not device or procedure-related but did result in a MACCE rate of 3.6% at six months. At twelve months there were two additional deaths, which were not device or procedure-related resulting in a MACCE rate of 10.7% at one year.

	30 days (n=30)		**6 months (n=28)**		**12 months (n=28)**	
MACCE (MI, stroke, death)	(0) 0.0	%	(1) 3.6	%	(3) 10.7	%
MI	(0) 0.0	%	(0) 0.0	%	(0) 0.0	%
stroke	(0) 0.0	%	(0) 0.0	%	(0) 0.0	%
death	(0) 0.0	%	(1) 3.6	%	(3) 10.7	%

CAS carries the risk of cerebral embolization during and following the procedure, leading to life-threatening complications, mainly cerebral ischemic events. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a sensitive tool used to identify cerebral emboli during CAS by measuring "lesions" within the brain which are areas that are ischemic and do not receive oxygenated blood due to cerebral emboli. In the CARENET trial, 37.0% of patients

treated with CGuard EPS had new ischemic lesions at 48 hours after the procedure, with an average volume of 0.039 cm^3. Of these lesions, there was only one that remained at 30 days following the procedure and all others had resolved. Complete details appear in the following table. Where there is a second number shown below after a ± symbol, it indicates the potential error in the measurement.

	48 hours	**30 days**
	n=27	**n=26**
Subjects with new Acute Ischemic Lesions (“AIL”)	10	1
Incidence of new lesions	37.0 %	4.0 %
Total number new AIL	83	1
Avg. number new AIL per patient	3.19 ± 10.33	0.04 ± 0.20
Average lesion volume (cm^3)	0.039 ± 0.08	0.08 ± 0.00
Maximum lesion volume (cm^3)	0.445	0.116
Permanent AIL at 30 days	—	1

The healing process of the tissue and in-stent restenosis can be measured by a non-invasive form of ultrasound called duplex ultrasound. This type of ultrasound measures the velocity of the blood that flows within the carotid arteries, which increases exponentially as the lumen of the internal carotid artery narrows and the percent stenosis increases. One of the measurements is called PSV (peak systolic volume) and is known to be highly correlated to the degree of in-stent restenosis; PSV values higher than 300 cm/sec are indicative of >70% stenosis, while PSV values lower than 104 cm/sec are indicative of <30% restenosis and healthy healing. In the CARENET trial, duplex ultrasound measurements done at 30 days, 6 months and 12 months following the stenting procedure all attest to healthy normal healing without restenosis concerns, as the PSV values were 60.96 cm/sec ± 22.31, 85.24 cm/sec ± 39.56, and 90.22 cm/sec ± 37.72 respectively. The internal carotid artery was patent in all patients (100%).

The conclusions of the CARENET trial were:

The CARENET trial demonstrated safety of the CGuard EPS stent, with a 30 day MACCE rate of 0%.

Incidence of new ipsilateral lesions (percent of patients with new lesions on the ipsilateral side (same side where the stent was employed)) at 48 hours was reduced by almost half compared to published data, and volume was reduced almost tenfold.

All but one lesion had resolved completely by 30 days.

Twelve month data showed no stroke or stroke-related deaths, and no cardiac adverse events.

CGuard EPS offers enhanced benefits for patients undergoing CAS with unprecedented safety.

Physician-Sponsored Clinical Trials for CGuard—PARADIGM-101 Study

PARADIGM-101 (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization **I**n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C**G**uard™ **M**esh-covered embolic prevention stent system-101) was an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine use of CGuard EPS in 101 consecutive unselected all-comer patients referred for carotid revascularization, initiated in 2015. In May 2016, the 30-day results were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, and in the Journal of EuroIntervention.

Key findings from the PARADIGM-101 study and the follow-up data are as follows:

CGuard EPS delivery success was 99.1%. The clinical evaluation also found no device foreshortening or elongation;

Angiographic diameter stenosis or vessel narrowing was reduced from 83±9% to only 6.7±5% ($p<0.001$);

Periprocedural death/major stroke/ myocardial infarction (“MI”) rates were 0%;

One event was adjudicated by the Clinical Events Committee as a minor stroke (0.9%), with no change in NIH Stroke Scale or modified Ranking scale;

The results of the PARADIGM-101 study demonstrated that CGuard EPS can safely be used in a high risk, all-comer population of patients with carotid artery stenosis and indicated that routine use of CGuard EPS may prevent cerebral events, such as strokes, by holding plaque against the vessel wall, preventing emboli from being released into the blood stream. The PARADIGM-101 study found that CGuard EPS is applicable in up to 90% of all-comer patients with carotid stenosis.

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study

"Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study" was an investigator-led, prospective single-center study which evaluated CGuard EPS in 30 consecutive patients with internal carotid artery stenosis disease with the objective of reporting early clinical outcomes with a novel MicroNetcovered stent for the internal carotid artery and the in vitro investigation of the device's mechanical properties. In October 2016, the 30-day positive results were published online-ahead-of-print in the Journal of Endovascular Therapy.

Key findings from the study are as follows:

- 100% success in implanting CGuard EPS without residual stenosis;
- No peri- or post-procedural complications;
- No deaths, major adverse events, minor or major strokes, or new neurologic symptoms during the six months following the procedure;
- Modified Rankin Scale improved for the symptomatic patients from 1.56 prior to the procedure to 0 afterwards;
- All vessels treated with CGuard EPS remained patent (open) at six months; and
- DW-MRI performed in 19 of 30 patients found no new ipsilateral lesions after 30 days and after six months compared with the baseline DW-MRI studies.

Additionally, based on engineering evaluations, the study concluded that CGuard EPS provides a high radial force and strong support in stenotic lesions. The stent is easy to use and safe to implant because it does not foreshorten and its structure adapts well to changes in diameter and direction of tortuous vascular anatomies. The MicroNet mesh of CGuard did not cause any changes to specific mechanical parameters of the underlying stent.

CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry

"CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry using CGuard EPS" was a physician initiated prospective multi-center registry that included 200 patients from 12 medical centers in Italy. The objective of the study was to report 30-day outcomes (including MACCE) in a prospective series of patients who were treated with CGuard EPS between April 2015 and June 2016. In January 2017, 30-day results were presented at the Leipzig Interventional Course (LINC) 2017 and published in the Journal of EuroIntervention in May 2017. The 12 month follow-up was published in the Journal of EuroIntevention in October 2018.

Key 30-day results presented were:

- 100% success in implanting CGuard EPS;
- No MI, major stroke or death at 30 days;
- There were two transient ischemic attacks and five periprocedural minor strokes, including one thrombosis solved by surgery.
- Total elimination of post-procedural neurologic complications by 30 days;
- DW-MRI performed pre-procedure and between 24 and 72 hours post-procedure in 61 patients, indicated that 12 patients had new micro emboli (19%).
- At 12 months, there were no new major neurological adverse events, thrombosis or external carotid occlusion recorded;
- One myocardial infarction occurred at 12 months.

Peri-procedural brain lesions prevention in CAS (3PCAS): Randomized trial comparing CGuard stent vs. WallStent™ Study

3PCAS study was an independent investigator-led single center randomized clinical trial, comparing CGuard EPS vs. WallStent™, intended to evaluate the incidence of peri-procedural diffusion-weighted-magnetic-resonance-imaging (DW-MRI) new brain lesions after carotid artery stenting. Sixty-one consecutive patients referred for carotid revascularization (between January 2015 and October 2016) were eligible for the study. The results of the 3PCAS study was published in the International Journal of Cardiology in September 2018. The discussion distinguished between peri-procedural (from procedure to 48h -72h) and post-procedural periods (72h to 30 days) where the CGuard EPS demonstrated a reduction in the post-procedural embolic effect during the carotid plaque healing period. In contrast, there was no difference between the two stent groups during the peri-procedural stage because of, according to the published article, the presence of bilateral/contralateral lesions (lesions resulting from the contralateral artery from the non-treated carotid) which suggest that the peri-procedural neurological damage may have originated from extra-carotid sources (outside of the artery which was treated and outside the stent itself).

Completed Clinical Trials for MGuard Bare-Metal Coronary Products

We have completed eight clinical trials with respect to our first generation stainless steel-based MGuard coronary device and our cobalt-chromium based MGuard Prime EPS stent. Our first generation MGuard stent combining the

MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union in October 2007. We subsequently replaced the stainless steel stent with a more advanced cobalt-chromium based stent for MGuard Prime EPS.

The First in Men (FIM) study conducted in Germany from the fourth quarter of 2006 through the second quarter of 2008 focused on patients with occlusion in their stent graft. This group is considered to be in “high risk” for complications during and shortly after the procedure due to the substantial risk of occurrence of a thromboembolic event. The study demonstrated MGuard’s safety in this high risk group. This study was followed by the GUARD study in Brazil in 2007 with a similar patient population which reinforced the safety profile of MGuard in patients prone to procedural complications. The MAGICAL study was a pilot study in STEMI patients conducted in Poland from 2008 through 2012 which demonstrated safety, measured by MACE rates at 30 days following the procedure, as well as efficacy results, measured by the ability of MGuard to reestablish blood flow into the infarcted area of the muscle. Furthermore, we conducted three registries (iMOS, IMR and iMOS Prime) that confirmed the feasibility of MGuard and MGuard Prime EPS for the treatment of STEMI patients and the safety of MGuard and MGuard Prime EPS in the STEMI patient group. Safety was repeatedly demonstrated in these trials and registries by the low mortality rate in the first month after the procedure.

In the second calendar quarter of 2011, we began the MGuard for Acute ST Elevation Reperfusion Trial (which we refer to as our “MASTER I trial”), a prospective, randomized study, which demonstrated that among patients with acute STEMI undergoing emergency PCI, patients treated with MGuard had superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution, or restoration of blood flow to the heart muscle after a heart attack, compared to those treated with commercially-approved bare metal or drug-eluting stents. The results of this trial are summarized in greater detail below.

Finally, the MASTER II trial, which we initially initiated as part of our efforts to seek approval of our MGuard Prime EPS by the U.S. Food and Drug Administration, was discontinued at our election in its current form in light of market conditions moving toward the use of drug-eluting stents over bare-metal stents. Analysis of the patients already enrolled in the MASTER II trial prior to its suspension, however, reconfirmed the MASTER I safety results due to a continued low mortality rate.

MASTER I Trial

In the second calendar quarter of 2011, we began the MASTER I trial, a prospective, randomized study in Europe, South America and Israel to compare the MGuard with commercially-approved bare metal and drug-eluting stents in achieving superior myocardial reperfusion (the restoration of blood flow) in primary angioplasty for the treatment of acute STEMI, the most severe form of heart attack. The MASTER I trial enrolled 433 subjects, 50% of whom were treated with MGuard and 50% of whom were treated with a commercially-approved bare metal or drug-eluting stents. The detailed acute and 30 days results from the trial were presented at the TCT conference on October 24, 2012 and published (Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh–Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction, Stone et. al, *JACC*, 60; 2012). The results were as follows:

- The primary endpoint of post-procedure complete ST-segment resolution (restoration of blood flow to the heart muscle after a heart attack) was statistically significantly improved in patients randomized to the MGuard compared to patients receiving a commercially-approved bare metal or drug-eluting stent (57.8% vs. 44.7%).

- Patients receiving MGuard exhibited superior rates of thrombolysis in myocardial infarction (TIMI) 3 flow, which evidences normal coronary blood flow that fills the distal coronary bed completely, as compared to patients receiving a commercially-approved bare metal or drug-eluting stent (91.7% vs. 82.9%), with comparable rates of myocardial blush grade 2 or 3 (83.9% vs. 84.7%) and corrected TIMI frame count (cTFC) (17.0 vs. 18.1

- Angiographic success rates (attainment of <50% final residual stenosis of the target lesion and final TIMI 3 flow) were higher in the MGuard group compared to commercially-approved bare metal or drug-eluting stents (91.7% vs 82.4%).

- Mortality (0% vs. 1.9%) and major adverse cardiac events (1.8% vs. 2.3%) at 30 days post procedure were not statistically significantly different between patients randomized to MGuard as opposed to patients randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard and commercially-approved bare metal or drug-eluting stents.

The six month results from the MASTER I trial were presented at the 2013 EuroPCR Meeting, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions, on May 23, 2013 in Paris, France. The results were as follows:

Mortality (0.5% vs. 2.8%) and major adverse cardiac events (5.2% vs. 3.4%) at 6 months post procedure were not statistically significantly different between patients randomized to the MGuard as compared to patients randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between patients treated with MGuard and those treated with commercially-approved bare metal or drug-eluting stents.

The twelve month results from the MASTER I trial were presented at the TCT conference on October 29, 2013 and published (Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial, Dudek et. al, *Coronary Interventions*, 2014). The results were as follows:

Mortality (1.0% vs. 3.3%) and major adverse cardiac events (9.1% vs. 3.3%) at 12 months post procedure were not statistically significantly different between patients randomized to the MGuard as opposed to those randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac events, as well as stent thrombosis, were comparable between the MGuard and commercially-approved bare metal or drug-eluting stents.

In summary, the MASTER I trial demonstrated that among patients with acute STEMI undergoing emergency PCI patients treated with MGuard had superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution compared to those treated with commercially-approved bare metal or drug-eluting stents. In addition, patients treated with MGuard showed a slightly lower mortality rate and a slightly higher major adverse cardiac event rate as compared to patients treated with commercially-approved bare metal or drug-eluting stents six and twelve months post procedure.

A detailed table with the results from the MASTER I trial is set forth below. The “p-Value” refers to the probability of obtaining a given test result. Any p value less than 0.05 is considered statistically significant.

	MGuard	**Bare Metal Stents/Drug Eluting Stents**	**p-Value**
Number of Patients	217	216	—
TIMI 0-1	1.8	5.6	0.01
TIMI 3	91.7	82.9	0.006
Myocardial blush grade 0-1	16.1	14.8	0.71
Myocardial blush grade 3	74.2	72.1	0.62
ST segment resolution >70	57.8	44.7	0.008
30 day major adverse cardiac event	1.8	2.3	0.75
6 month major adverse cardiac event	5.2	3.4	0.34
12 month major adverse cardiac event	9.1	3.3	0.02

Future Clinical Trials for CGuard EPS and MGuard Prime EPS

Post-marketing clinical trials (outside the United States) could be conducted to further evaluate the safety and efficacy of CGuard EPS in specific indications. These trials would be designed to facilitate market acceptance and expand the use of the product. We expect to be able to rely upon CE mark approval of the product and other supporting clinical data to obtain local approvals.

We do not anticipate conducting additional post-marketing clinical trials for our bare-metal MGuard coronary products.

Growth Strategy

Our primary business objective is to utilize our proprietary MicroNet technology and products to become the industry standard for treatment of stroke, complex vascular and coronary disease and to provide a superior solution to the common acute problems caused by current stenting procedures, such as restenosis, embolic showers and late thrombosis. We are pursuing the following business strategies to achieve this objective.

Widen the adoption of CGuard EPS. We are seeking to transition current users of conventional carotid stents to use CGuard EPS and to convince vascular surgeons to use CGuard EPS in filter protected carotid artery stenting instead of vascular surgery in appropriate patients. We publish and present our clinical data and support investigator-initiated clinical registries, which we plan to continue and expand. We have partnered and will continue to seek out partnerships with appropriate societies focused on the treatment of stroke. We will also continue to engage advisory boards and to develop a network of key opinion leaders to assist us in widening the adoption of CGuard EPS.

Grow our presence in existing and new markets for CGuard EPS. We have launched CGuard EPS in most European and Latin American countries through a comprehensive distributor sales organizations network. We will continue to focus on larger growing markets through this network by supporting our distributors with a comprehensive marketing and clinical education programs. In November 2018, we obtained approval for reimbursement and commercial sale for CGuard EPS in Australia and we are planning to launch there in 2019. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, the Middle East, Asia and Latin America. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

Continue to leverage our MicroNet technology to develop additional applications for interventional cardiologists and vascular surgeons. In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary MicroNet technology to address imminent market needs for new product innovations to significantly improve patients' care. We continue to broadly develop and protect intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease, neurovascular disease, renal artery disease and bifurcation disease.

Establish relationships with collaborative and development partners to fully develop and market our existing and future products. We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and MGuard DES, and other potential products that are based on our MicroNet technology.

Continue to protect and expand our portfolio of patents. Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Seventeen patent applications have been filed (seven of which are now pending) in the United States, some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products and may be useful for protecting our future technological developments. We intend to aggressively continue patenting new technology, and to actively pursue any infringement covered by any of our patents. We believe that our patents, and patent applications once allowed, are important for maintaining the competitive differentiation of our products and maximizing our return on research and development investments.

Resume development and successfully commercialize MGuard DES. While we have limited the focus of product development to our carotid products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop MGuard DES.

Competition

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants.

Carotid

The carotid stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), and Cordis Corporation (currently part of Cardinal Health, Inc.). Gore Medical and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent, respectively. All of these larger companies have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have established reputations and relationships with our target customers, as well as worldwide distribution methods that are more effective than ours. However, we believe that the European market is somewhat fragmented, and, in our opinion, smaller competitors may be able to gain market share with greater flexibility.

Coronary

The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, and Medtronic, Inc. In Europe, the market is now almost exclusively dominated by drug eluding stents and is rapidly becoming so in the rest of the world. (Catheter Cardiovasc Interv. 2018 Oct 1;(92(4):E262-E270. doi: 10.1002/ccd.27375. Epub 2017 Oct 13. https://www.ncbi.nlm.nih.gov/pubmed/29027735). We believe physicians look to next-generation stent technology to compete with existing therapies. Such next-generation technologies include bio-absorbable stents, stents that focus on treating bifurcated lesions, and stents with superior polymer and drug coatings, and many industry participants are working to improve stenting procedures as the portfolio of available stent technologies rapidly increases.

According to the MEDTECH OUTLOOK, the three major players (Abbott Laboratories, Boston Scientific Corporation and Medtronic, Inc.) in the worldwide coronary stent market have a combined total market share of approximately 92%. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to further our product growth is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. Due to ongoing consolidation in the industry, there are high barriers to entry for small manufacturers in the European and the U.S. markets and the rest of the world.

Neurovascular

Leading industry players in the global neurovascular devices market include Medtronic, Stryker, Terumo and Johnson & Johnson. Acquisitions and mergers are increasingly used as a strategy for product portfolio expansion and to grow footprint. (Global Market Insights, Inc. - Devices Market Share 2018-2024 Industry Size Report. https://www.gminsights.com/industry-analysis/neurovascular-devices-market)

Sales and Marketing

Sales and Marketing

Currently, we are actively selling our MGuard coronary products with a bio-stable MicroNet through local distributors in Europe, Latin America, the Middle East and Asia.

Based on the positive CGuard EPS clinical data, we initiated the commercial launch of CGuard EPS in CE marked countries in early 2015. In September 2015, we announced full market launch of CGuard EPS in Europe.

In 2017, we decided to shift our commercial strategy to focus on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Pursuant to this strategy, we completed our transition away from a single distributor covering 18 European countries to a direct distribution model. Through our former distributor in Europe, CGuard EPS was largely sold to interventional neuroradiologists. Our current strategy is intended to broaden our sales efforts to transition vascular surgeons from carotid endarterectomy procedures to carotid stenting with CGuard EPS, which we believe can greatly expand our customer base. We have focused and we plan to continue to focus our marketing efforts primarily on key growth markets and to evaluate opportunities in new territories if and when they become available. We have expanded our clinical support team to support new customers and accelerate growth. In addition, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We continue to work with leading physicians to enhance our marketing effort and are developing relationships with new key opinion leaders to champion our technology and work with us in clinical studies

Product Positioning

The MGuard coronary products have initially penetrated the market by entering segments with indications that present high risks of embolic dislodgement, notably acute MI and saphenous vein graft coronary interventions. Even though MGuard technology has demonstrated its advantages with clinical data, it is based on a bare-metal platform while the market demand has shifted away from bare-metal stents in favor of drug-eluting stents.

When treating carotid artery disease, we believe that there is an opportunity to enter the market with bare-metal stent platform and to become a competitive player without a drug-eluting stent platform. Therefore, we believe that CGuard EPS is poised for commercial growth in 2019 as more and more positive clinical data is presented. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval within three calendar quarters of receiving such proceeds. Based on the level of interest in this product that we have observed in our clinical trials, we believe that CGuard EPS with a smaller profile delivery catheter will enable us to meet the market demand for minimally invasive devices, which, we believe, may have broader and easier usage, and for a lower profile system used in procedures in which predilation could be problematic. We also believe that CGuard EPS with a smaller profile delivery catheter will enable us to have a competitive advantage in penetrating the Asia Pacific market, since its population is generally smaller than in Western countries. In addition, we believe that CGuard EPS with a smaller profile delivery catheter will enable us to offer CGuard EPS for use in transradial catheterization, which, we believe, is gaining favor among interventionalists. Finally, we do not expect that it would be crucial to use a drug-eluting stent platform to compete in certain new markets such as the neurovascular market, and hence, we plan to continue to explore this area of opportunity.

Insurance Reimbursement

In most countries, a significant portion of a patient's medical expenses is covered by third-party payors. Third-party payors can include both government funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, payors, in many instances, have similarly established policies, and in the U.S., for example, coverage policies and reimbursement rates of private payors are often influenced by those established by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS). The MGuard coronary products and CGuard products sold to-date in applicable foreign countries have been designed and labeled to facilitate the utilization of existing reimbursement codes for such countries, and we intend to continue to design and label our present and future products in a manner consistent with this goal.

While most countries have established reimbursement codes for stenting procedures, certain countries may require additional clinical data before recognizing coverage and/or to obtain a certain level of reimbursement for one or more of our products. In these situations, we intend to complete the required clinical studies to obtain reimbursement approval in countries where it makes economic sense to do so.

Intellectual Property

Patents

We have twenty-nine pending patent applications, seven of which are pending in the United States, many of which cover aspects of our MGuard and CGuard technology. Some of the corresponding patent applications outside the U.S. are filed in Canada, China, Europe, Israel, India and South Africa. We hold an aggregate total of over 80 patents and pending applications including twelve issued U.S. patents. These patent rights are directed to cover various patent families, including the following seven (7) patent families:

Base Title of Patent Family	Country Pending	Country/Patent No.	Issue Date
		Israel 198,188	5/1/2014
Bifurcated Stent Assemblies			
		China ZL200780046676.2	9/26/2012
	US	—	—
Deformable Tip for Stent Delivery and Methods of Use			
	Brazil	—	—
	Canada	—	—
	China	—	—
	EPO	—	—
	Israel	—	—
	India	—	—
	Japan	—	—
	Mexico	—	—
	Russia	—	—

In Vivo Filter Assembly	India	Canada 2,666,712	
		Canada 2,881,557	3/31/2015
		US 8,043,323	10/11/2016
		US 9,132,261	10/25/2011
		Israel 198,189	9/15/2015
		China ZL200780046659.9	2/1/2014
		China ZL201210119132.7	6/13/2012
			6/24/2015
		EP 07827228.3 (Germany, France, & UK)	8/30/2017
Knitted Stent Jackets	India	Canada 2,666,728	
		Canada 2,887,189	6/23/2015
		China ZL200780046697.4	5/1/2018
		China ZL201210320950.3	10/10/2012
		Israel 198,190	12/2/2015
		EP 07827229.1 (Germany, France, & UK)	2/1/2014
			3/29/2017
			11/27/2018
Optimized Stent Jacket	Canada EPO Israel US	US 10,137,015 Canada 2,670,724 China ZL201210454357.8 China ZL200780043259.2 India 297,257	12/11/2018 12/9/2015 1/2/2013 5/30/2018 5/28/2014

		Israel 198,665	9/15/2015
		US 9,132,003	12/27/2016
		US 9,526,644	10/10/2017
		US 9,782,281	10/11/2017
		EP 07827415.6 (10 EP countries)	
		South Africa 2007/10751	10/27/2010
Stent Apparatuses for Treatment Via Body Lumens and Methods of Use	US	Canada 2609687	4/22/2015
	Israel	Canada 2,843,097	10/27/2015
	Europe (EPO)	US 8,961,586	2/24/2015
		US 10,058,440	8/28/2018
	Australia	US 10,070,977	9/11/2018
	Canada		
Stent Thermoforming Apparatus and Methods	Europe (EPO)	US 9,527,234	12/27/2016
	India	US 9,782,278	10/10/2017
	Japan		
	US		

In lay terms, these patent applications generally cover three aspects of our products: the mesh sleeve with and without a drug, the product and the delivery mechanism of the stent. We also believe that one or more additional pending patent applications, upon issuance, will cover our existing products. We also believe that the patent applications we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, if issued as patents with claims substantially in their present form, would likely create a significant barrier for another company seeking to use similar technology.

Trade Secrets

We also rely on trade secret protection to protect our interests in proprietary know-how and/or for processes for which patents are difficult to obtain or enforce. As part of this, we rely on non-disclosure and confidentiality agreements

with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology.

Trademarks

We use the InspireMD®, MGuard®, CGuard®, and MGuard Prime® trademarks in connection with our products. We have registered these trademarks in the European Union. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have registrations for Carenet®, NGuard®, PVGuard® and the MNP Micronet Protection Logo in the European Union and a supplemental registration for Micronet® in the United States. We have also applied to register the names PVGuard™ as a trademark in the European Union, as well as Carenet™, CGuard™ InspireMD™, SmartFit™, PVGuard™, NGuard™, AGuard™, and MGuard Prime™ as trademarks in the United States. We also use and may have common law rights to various trademarks, trade names, and service marks.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the European Union CE mark and other corresponding foreign agencies.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex approval process, clinical trials and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain U.S. Food and Drug Administration market authorization. These differences may affect the timeliness of international market introduction of our products. For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, we must comply with the Medical Device Directive 93/42/EEC by presenting comprehensive technical files for our products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by an European Notified Body. We have obtained ISO 13485 quality system certification and the products we currently distribute into the European Union display the required CE mark. In order to maintain certification, we are required to pass an annual surveillance audit conducted by Notified Body auditors.

As noted below, we have or had regulatory approval and made sales of MGuard Prime EPS, CGuard EPS or both products either through distributors pursuant to distribution agreements or directly, in the following countries: Argentina, Australia, Austria, Belarus, Belgium, Brazil, Bulgaria, Chile, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hong Kong, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Netherlands, Norway, Peru, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey Vietnam and the United Kingdom In addition, we are awaiting regulatory approval to sell our products in Taiwan. While each of the European Union member countries accepts the CE mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we

believe that certain of the above-listed countries that are not members of the European Union accept the CE mark as a primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of our products. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America, however, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months or more, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

In October 2007, our first generation MGuard stent combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union. We subsequently replaced the first generation MGuard product with MGuard Prime EPS, which uses a more advanced cobalt-chromium based stent. Our MGuard Prime EPS received CE mark approval in the European Union in October 2010 and marketing approval in those countries listed in the table below.

The CGuard EPS received CE mark approval in the European Union on March 14, 2013 and marketing approval in the countries listed in the table below. We are currently seeking marketing approval for CGuard EPS in, South Korea and Taiwan.

Please refer to the table below setting forth the approvals and sales made for CGuard EPS and the MGuard Prime EPS on a country-by-country basis.

Approvals and Sales of MGuard Prime EPS and CGuard EPS on a Country-by-Country Basis

Countries	MGuard Prime EPS Approval	MGuard Prime EPS Sales	CGuard EPS Approval	CGuard EPS Sales
Argentina	Y	Y	Y	Y
Australia	N	Y	(1) Y	Y
Austria	Y	Y	Y	Y
Belarus	Y	Y	Y	Y
Belgium	Y	Y	Y	Y
Brazil	Y	Y	N	N
Bulgaria	Y	Y	Y	Y
Chile	N	Y	(2) Y	Y
Colombia	Y	Y	Y	Y
Croatia	Y	Y	Y	N
Cyprus	Y	Y	Y	Y
Czech Republic	Y	Y	Y	Y
Denmark	Y	N	Y	Y
Dominican Republic	Y	Y	Y	Y
Ecuador	Y	Y	Y	Y
Estonia	Y	Y	Y	Y
Finland	Y	Y	Y	Y
France	Y	Y	Y	Y
Germany	Y	Y	Y	Y
Greece	Y	N	Y	Y
Holland (Netherlands)	Y	Y	Y	Y
Hong Kong	N	N	Y	Y
Hungary	Y	Y	Y	Y
Iceland	Y	N	Y	N
India	Y	N	Y	Y
Ireland	Y	Y	Y	N
Israel	Y	Y	Y	Y
Italy	Y	Y	Y	Y
Latvia	Y	Y	Y	Y
Lithuania	Y	Y	Y	Y
Liechtenstein	Y	N	Y	N
Luxembourg	Y	Y	Y	N
Malaysia	Y	Y	Y	N
Malta	Y	Y	Y	N

Mexico	Y	Y	Y	Y
Norway	Y	Y	Y	N
Peru	Y	N	Y	Y
Poland	Y	Y	Y	Y
Portugal	Y	N	Y	Y
Romania	Y	Y	Y	Y
Russia	Y	Y	Y	Y
Saudi Arabia	N	Y	(3) N	N
Serbia	Y	N	Y	Y
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y	(4) Y	Y	N
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	Y
Switzerland	Y	Y	Y	