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**