

InspireMD, Inc.  
Form 10-K  
March 12, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-K**

**(Mark One)**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

**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**  
(State or other jurisdiction of  
incorporation or organization)

**26-2123838**  
(I.R.S. Employer Identification Number)

**321 Columbus Avenue**  
**Boston, Massachusetts 02116**  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(857) 453-6553**

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value	NYSE MKT

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 ☒

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 ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ 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. ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2014, based on the price at which the common equity was last sold on the NYSE MKT on such date, was approximately \$90,786,938. 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 March 11, 2015
Common Stock, \$0.0001 par value	78,152,015

**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 coronary and vascular 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 initial MGuard coronary products (MGuard and MGuard Prime Embolic Protection Stent (EPS)) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

#### **MGuard Sleeve – Microscopic View**

We market and sell our bare-metal MGuard products in the European Union, Southeast Asia, India, Latin America and Israel. 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 stainless steel stent with a more advanced cobalt-chromium based stent. Our cobalt-chromium based MGuard coronary product is referred to as the MGuard Prime EPS and, unless otherwise indicated, in this Annual Report on Form 10-K, references to bare-metal MGuard coronary stents are to both our initial stainless steel based MGuard coronary product and our more current cobalt-chromium based MGuard Prime EPS. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection.

In October 2014, we launched a limited market release of our second product CGuard carotid embolic prevention system (“EPS”) in certain European countries. CGuard EPS combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease. CGuard EPS received CE mark approval in the European Union in March

2013. In January 2015, we received CE mark approval for our CGuard RX rapid exchange delivery system for its Micronet covered embolic prevention system. The new RX delivery system will enable clinicians to place the CGuard technology using an easy-to-use, and familiar, delivery system. The CGuard MicroNet mesh covered carotid stent remains unchanged.

We are also developing a pipeline of other products and additional applications by leveraging our MicroNet technology. Among the products in development is a coronary stent product incorporating drug-eluting (drug-coated) stents with MicroNet, for which in vivo pre-clinical testing began in the fourth calendar quarter of 2014 and will continue through 2015. We also intend to explore possible new applications of our technology in other vascular procedures and interventional medical specialties, specifically peripheral and neurovascular procedures.

Presently, none of our products may be sold or marketed in the U.S.

We make available, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports on our website at [www.inspire-md.com](http://www.inspire-md.com) as soon as reasonably practicable after those reports and other information is electronically filed with, or furnished to, the SEC.

### **Voluntary Field Action**

On April 30, 2014, we initiated a voluntary field corrective action of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements. These reported dislodgements primarily occurred during the preparation of the MGuard Prime EPS, upon removal of the protective sleeve or during withdrawal of the MGuard Prime EPS into the guide catheter. To address this problem, we subsequently modified our manufacturing process of MGuard Prime EPS stents in order to improve stent retention and performance. We received approvals from the European regulatory agency and the U.S. Food and Drug Administration to resume the manufacturing of the MGuard Prime EPS stent with a modified stent securement process on June 18, 2014 and October 23, 2014, respectively. We also received approval to modify and re-deploy existing MGuard Prime EPS stents that had been returned to us by clinical and commercial sites worldwide. All returned inventory has been modified and returned to direct hospital customers and the majority of our distributor partners, who have begun shipping modified product back into hospital accounts. We began shipping products to new customers in our direct markets in Western Europe in late September 2014 and intend to complete the full re-launch of MGuard Prime EPS in 2015.

### **Business Segment and Geographic Areas**

Prior to October 2014, all revenue was derived from sales of our MGuard bare-metal stent. For the twelve months ended December 31, 2014, 99% of our revenue was derived from sales of this product. For financial information about our one operating and reportable segment and geographic areas, refer to “Part II—Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Part II—Financial Statements and Supplementary Data—Note 12 - Entity Wide Disclosures.”

### **Our Industry**

#### ***Coronary***

Physicians and patients may select from among 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.

Coronary artery disease is one of the leading causes of death worldwide. According to Fact Sheet No. 310/updated May 2014 of the World Health Organization, approximately 7.4 million people worldwide died of ischaemic heart disease in 2012. The treatment of coronary artery disease includes alternative treatment methodologies, that is, coronary artery bypass grafting or angioplasty (a therapeutic procedure to treat narrowed coronary arteries of the heart found in patients with heart disease) with or without stenting. According to the MEDTECH OUTLOOK, the PCI procedures involving stents used to treat coronary artery diseases had an estimated 68% market penetration rate in 2013.

### *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 Fact Sheet No. 310, approximately 6.7 million people worldwide died of stroke in 2012.

The global market value of carotid stents is approximately \$500 million, approximately \$300 million of which consists of the U.S. market and approximately \$200 million of which consists of the rest of the world. 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 through an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and EPS protect against plaque and debris traveling downstream, blocking off the vessel and disrupting blood flow. The use of a stent with an embolic protection system avoids open surgery and we believe will increase the number of patients being treated.





## ***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 (PAOD) or peripheral artery disease (PAD). 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 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, PTA 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 scarring 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 alcohols 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.

The MGuard stent is an embolic protection device based on a protective sleeve, which is constructed out of an ultra-thin polymer mesh and wrapped around the stent. The protective sleeve is comprised of a micron level fiber-knitted mesh, engineered in an optimal geometric configuration and designed for utmost flexibility while retaining strength characteristics of the fiber material (see illustration below). The sleeve expands seamlessly when the stent is deployed, without affecting the structural integrity of the stent, and can be securely mounted on any type of stent.

### **MGuard Deployed in Artery**

The protective sleeve is designed to provide several clinical benefits:

- the mesh diffuses the pressure and the impact of deployment exerted by the stent on the arterial wall and reduces the injury to the vessel;

- the protective sleeve reduces plaque dislodgement and blocks debris from entering the bloodstream during and post procedure (called embolic showers);

- in future products, when drug coated, the mesh is expected to deliver better coverage and uniform drug distribution on the arterial wall and therefore potentially reduce the dosage of the active ingredient when compared to approved drug-eluting stents on the market; and

- the protective sleeve maintains the standards of a conventional stent and therefore should require little to no additional training by physicians.

## **MGuard Products– Coronary Applications**

Our MGuard Coronary with a bio-stable mesh and our planned MGuard Coronary with a drug-eluting mesh are aimed at the treatment of coronary arterial disease.

***Bare-Metal Stent MGuard Products.*** Our MGuard stent and MGuard Prime EPS are comprised of MicroNet wrapped around a bare-metal stent. In comparison to a conventional bare-metal stent, we believe our MGuard coronary products with MicroNet mesh provide 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”), the most severe type of heart attack. 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.

We have studied over 1,200 patients who were treated with our MGuard products. In the second calendar quarter of 2011, we conducted the MGuard for Acute ST Elevation Reperfusion trial, which we refer to as our “MASTER I trial.” The Master I trial was a prospective, randomized study in Europe, South America and Israel to compare the MGuard stent 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 MASTER I trial enrolled 433 subjects, 50% of whom were treated with an MGuard stent and 50% of whom were treated with a commercially-approved bare-metal or drug-eluting stent. The MASTER I trial demonstrated that among patients with acute STEMI undergoing emergency PCI, or angioplasty, use of the MGuard stent resulted in superior rates of epicardial coronary flow, or 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 commercially-approved bare-metal or drug-eluting stents. Although each of MGuard stents and commercially-approved bare-metal or drug-eluting stents showed statistically similar rates of major adverse cardiac events 30 days following the procedure, the mortality rate was 0% for the subjects treated with the MGuard stent as opposed to 1.8% for the subjects treated with commercially-approved bare-metal or drug-eluting stents 30 days following the procedure.

In connection with our efforts to seek approval of our MGuard Prime EPS by the U.S. Food and Drug Administration, we filed an IDE application with the U.S. Food and Drug Administration during the summer of 2012 in order to conduct a pivotal trial. On April 19, 2013, we received an approval with conditions from the U.S. Food and Drug Administration for our IDE application, which allowed us to initiate enrollment in the trial. This trial, which we refer to as the “MASTER II trial,” was expected to be a multi-center, randomized study, consisting of up to 1,114 patients suffering from STEMI throughout 35 sites in the U.S. and an additional 35 sites in Europe. The MASTER II trial was designed to have two co-primary end points: superiority in complete ST-resolution and non-inferiority in death and target vessel myocardial infarction. In addition, a sub-study was planned to assess the effect of MGuard Prime EPS on

infarct size, as measured by magnetic resonance imaging, and an additional sub-study was to be conducted to assess the late lumen loss, measured at 13 months. We successfully enrolled 310 patients in the trial prior to suspending enrollment in April 2014 due to manufacturing process changes in connection with the voluntary field correction action, pending a review by the U.S. Food and Drug Administration of the manufacturing improvements to the MGuard Prime EPS. The U.S. Food and Drug Administration approved the re-commencement of the MASTER II trial in October 2014. However, we elected to discontinue enrollment in the MASTER II trial in its current form, in light of current market conditions moving toward the use of drug-eluting stents over bare-metal stents, and MASTER II will no longer be a U.S. Food and Drug registration trial. Notwithstanding the discontinuance of the enrollment for the MASTER II trial, the preliminary analysis of the 30-day end point data from the 310 patients enrolled prior to the suspension of the enrollment is encouraging. We intend to continue to follow these 310 MASTER II trial patients for one year from time of enrollment. The 30 day results from the MASTER II Trial were presented at the ICI meeting in Tel-Aviv, Israel in 2014. There were no significant differences in procedural and clinical endpoints, most likely due to the small group size which is too small to find any statistical differences.

A 30 day pooled analysis of MASTER I and MASTER II trial results was presented at the ICI meeting in Tel-Aviv, Israel in 2014 and the results clearly showed that MGuard demonstrated a significant reduction in all-cause and cardiac mortality at 30 days (MGuard 0.3% vs. Control 1.9%;  $p=0.04$ ) compared to conventional bare metal or drug eluting stents.

The 30 day and six month results from the International MGuard Prime Observational Study (“iMos”) were also presented at the ICI meeting in December 2014. The iMOS registry seeks to evaluate the ‘real world’ clinical performance of the MGuard Prime EPS in STEMI patients undergoing percutaneous coronary intervention. The 30 day and six month results indicate that MGuard Prime EPS is feasible, based on 100% device and lesion success rates, and safe, based on no deaths at 30 days follow-up, two deaths at six month follow-up and very low MACE rates at 30 days and six month follow-up. The use of the MGuard Prime EPS seemed also highly effective in achieving myocardial reperfusion, as suggested by the high rates of TIMI-3 flow (91.8%) and partial or complete STR (87%).

Recently we began enrollment in a multi-center, single-arm post-market registry of 500 patients with STEMI to collect post-CE mark trial clinical data on patients treated with MGuard Prime EPS from 50 planned sites across Europe, which we refer to as our “eMASTER study.” We plan to evaluate the safety and efficacy of the MGuard Prime EPS in the treatment of de novo stenotic lesions in coronary arteries in patients undergoing PCI due to STEMI, based on patients with complete ST-segment resolution and rates of all-cause death or myocardial infarction at 30 days.

***Drug-Eluting Stent (or “DES”) MicroNet Product.*** We recently entered the second phase of development work for our MGuard DES, which is expected to incorporate our MicroNet with a drug-eluting stent, through a strategic partnership with a third party drug-eluting stent candidate manufacturer. We intend to develop a total of two strategic partnerships with manufactures of U.S. Food and Drug Administration-approved or CE-marked drug-eluting stents and bring two viable drug-eluting stent products with our MicroNet mesh into the in vivo pre-clinical testing phase which, if successful, should lead to submission for CE registration of a DES-MicroNet platform. The initial testing of drug-eluting stent candidates for technical feasibility testing with our MicroNet mesh was 100% successful. We believe that a drug-eluting stent with MicroNet has the potential to improve certain performance metrics over the MGuard Prime and attract a broader portion of the cardiologists in the worldwide stent market who are more accustomed to using drug-eluting stents.

### **CGuard – Carotid Applications**

In October 2014, we initiated a limited market release of CGuard EPS, which is comprised of our MicroNet mesh and a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in carotid artery applications. We launched CGuard EPS in Germany, Poland, Switzerland, Belgium, Italy and Spain. 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 to 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 technology is a highly flexible stent system that easily conforms to the carotid anatomy.

In September 2014, we reported the results of the CARENET trial at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Washington D.C. In the CARENET trial, the CGuard system demonstrated better results over historical data using conventional commercially available carotid stents.

We believe that our CGuard EPS design will provide substantial 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.

The full launch of the CGuard EPS will occur concurrently with the introduction of the new rapid exchange delivery system for CGuard EPS. Since July 2014, we have been working on our next generation rapid exchange delivery system, which is the type of delivery system the majority of physicians that place carotid stents prefer. Our CGuard

EPS is currently sold with the over-the-wire delivery system. An over-the-wire delivery system has two lumens and ports. The guide wire lumen and port exists independent of the other lumen for stent delivery and thus two operators must perform the procedure. A rapid exchange delivery system, on the other hand, has a guide wire that passes through the delivery system, running through the guiding catheter. It has one port and thus can be operated by one operator, and as such, can require less time to complete the procedure. The length of the guide wire required for the rapid exchange delivery system is significantly shorter than for the over-the-wire delivery system, and as such, an ordinary guiding wire can be used without adding an extension wire. Our rapid exchange delivery system recently received CE mark approval in January 2015. We plan to focus our full launch of the CGuard on countries in the European Union and Latin America. We will primarily target high volume centers in core European markets. We intend to market and sell our CGuard EPS for use in multiple medical specialties that perform carotid artery stenting. These customers would include interventional cardiologists, vascular surgeons, interventional neuroradiologists and interventional radiologists. The full launch of our CGuard EPS will not include the U.S. We are preparing materials required to conduct a clinical trial in the U.S. Once complete, we will request a pre-submission guidance meeting with the U.S. Food and Drug Administration.

### **PVGuard — Peripheral Vascular Applications**

We intend to develop our MicroNet mesh sleeve and a self-expandable stent for use in peripheral vascular applications. Peripheral artery disease, also known as peripheral vascular disease, is 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. Peripheral artery disease 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.

## Product Development and Critical Milestones

Below is a list of the products described above and our projected critical milestones with respect to each. As used below, “CQ” stands for calendar quarter (e.g., “CQ1-2015” means January 1, 2015 through March 31, 2015). The use of the term “to be determined” in the table below with regard to certain milestones indicates that the achievements of such milestones is unable to be accurately predicted as such milestones are too far in the future.

<b>Product</b>	<b>Indication</b>	<b>CE Mark</b>	<b>European Union Sales</b>	<b>FDA Approval(1)</b>	<b>U.S. Sales</b>
MGuard stent (bare-metal stent)	Bypass/Coronary	Oct. 2007	CQ1-2008	To be determined	To be determined
Drug-Eluting Stent with MicroNet	Bypass/Coronary	To be determined	To be determined	To be determined	To be determined
CGuard Carotid	Carotid Arteries	March 2013	Oct. 2014	To be determined	To be determined

(1) We anticipate that the MGuard and CGuard products will be classified as Class III medical devices by the U.S. Food and Drug Administration.

## Pre-Clinical Studies

We performed laboratory and in vivo pre-clinical testing prior to submitting an application for CE Mark approval for our MGuard Coronary stent with MicroNet. We also performed all CE Mark-required mechanical testing of the stent and delivery system. We conducted in vivo pre-clinical studies at the CBSET lab (Lexington, MA) in July 2006 and August 2007. In these studies, on average, the performance of the MGuard Coronary stent with MicroNet was comparable with the performance of control commercially available bare-metal stents. Analysis also indicated that in these studies, the MGuard with MicroNet had comparable biological responses to those of control commercially available bare-metal stents. No human trials were conducted as part of these pre-clinical studies.

The table below describes our completed and planned pre-clinical in vivo studies. The use of the term “To be determined” in the table below with regard to milestone dates in our in vivo pre-clinical studies indicates that we have not yet decided when to schedule such milestones.



<b>Product</b>	<b>Stent Platform</b>	<b>Approval Requirement</b>	<b>Start of Study</b>	<b>End of Study</b>
MGuard stent	Bare-Metal Stent Plus Bio-Stable MicroNet	CE Mark (European Union + Rest of World)	CQ4-2006	CQ3-2007
	Mesh			
	Drug-Eluting Stent with MicroNet	CE Mark (European Union + Rest of World)	To be determined	To be determined
		FDA (U.S.)	To be determined	To be determined
MGuard Prime EPS	Cobalt-Chromium Stent Plus MicroNet	FDA (U.S.)	CQ2-2011	CQ2-2012
	Mesh			
MGuard Peripheral/Carotid	Self-Expanding Stent System Plus MicroNet	CE Mark (European Union + Rest of World)	CQ4-2012	CQ2-2013

With respect to the preclinical studies for MGuard Coronary with a drug eluting bio-absorbable mesh, the trials have been indefinitely suspended due to our determination to focus our time and resources on other trials at this time.

## Clinical Trials

The table below describes our completed and planned clinical trials. The use of the term “To be determined” in the table below with regard to milestone dates in our clinical trials indicates that we have not yet decided when to schedule such milestones. All milestone dates set forth in the table below are our best estimates based upon the current status of each clinical trial.

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	Study Status			
					No. of Patients	Start Enrollment	End Enrollment	End of Study
MGuard Coronary	Bare-Metal Stent Plus MicroNet	Germany – two sites	12 months	Study to evaluate safety and performance of MGuard system	41	CQ4-2006	CQ4-2007	CQ2-2008
		Brazil – one site	12 months	See above	30	CQ4-2007	CQ1-2008	CQ2-2008
		Poland – four sites	3 years	See above	60	CQ2-2008	CQ3-2008	CQ3-2011
		International MGuard Observational Study – worldwide – 19 sites	12 months	See above	550	CQ1-2009	CQ1-2013	CQ1-2013
		Israeli MGuard Observational Study – Israel – 9 sites	6 months	See above	87	CQ4-2009	CQ1-2013	CQ3-2013
		Master randomized control trial – 9 countries, 50 centers in South America, Europe and Israel	13 months	See above	433	CQ2-2011	CQ2-2012	CQ3-2013
		MASTER-II – 70 sites, U.S. and out of U.S.	13 months	Pivotal study to evaluate safety and performance of MGuard Prime EPS system for FDA approval	1,114	CQ3-2013	Enrollment discontinued	N/A
		iMOS Prime 2 sites in the Netherlands	12 months	Post-market registry of MGuard Prime EPS	97	CQ4-2012	CQ1-2014	CQ1-2014

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		eMASTER	12 months	Post-market registry of MGuard Prime EPS	500	CQ2-2014	To be determined	To be determin
		CARENET		Evaluation of safety and efficacy for specific indications				
CGuard Carotid	Self-Expanding Carotid Stent Plus MicroNet	Post approval registry study 4 sites in Europe	12 months	post- marketing Study to evaluate safety and performance of MGuard system for CE Mark approval	30	CQ2-2014	CQ3-2014	CQ3-20
MGuard Peripheral	Self-Expanding Stent System Plus MicroNet	Possibly South America and Europe –			To be determined	To be determined	To be determined	To be determin

Each of the patient numbers and study dates set forth in the tables above are management's best estimate of the timing and scope of each referenced trial. Actual dates and patient numbers may vary depending on a number of factors, including, without limitation, feedback from reviewing regulatory authorities, unanticipated delays by us, regulatory authorities or third party contractors, actual funding for the trials at the time of trial initiation and initial trial results.

With respect to the MASTER II trial, we successfully enrolled 310 patients in the trial prior to suspending enrollment in April 2014 due to manufacturing process changes in connection with the voluntary field correction action, pending a review by the U.S. Food and Drug Administration of the manufacturing improvements to the MGuard Prime EPS. The U.S. Food and Drug Administration approved the re-commencement of the MASTER II trial in October 2014. However, we elected to discontinue enrollment in the MASTER II trial in its current form, in light of current market conditions moving toward the use of drug-eluting stents over bare-metal stents, and MASTER II will no longer be a U.S. Food and Drug registration trial. Notwithstanding the discontinuance of the enrollment for the MASTER II trial, we intend to continue to follow these 310 MASTER II trial patients for one year from time of enrollment. This follow-up is expected to be completed in June 2015.

The drug eluting stent with MicroNet's clinical trials have been delayed from our previously announced target until additional funding is secured through potential strategic partnerships.

With respect to the MGuard Peripheral clinical trial for the self-expanding system plus MicroNet, the start date has been delayed from our previously announced start date until additional funding is secured.

### **Completed Clinical Trials for MGuard Bare-Metal Coronary Stent Plus MicroNet**

As shown in the table above, we have completed six clinical trials with respect to our MGuard coronary stent. Our first study, conducted at two centers in Germany, included 41 patients requiring either saphenous vein graft interventions or having native coronary lesions that could be treated by a stenting procedure (blockages where no bypass procedure was performed). The MGuard rate of device success, meaning the stent was successfully deployed in the target lesion, was 100% and the rate of procedural success, meaning there were no major adverse cardiac events prior to hospital discharge, was 95.1%. At six months, only one patient (2.4% of participants) had major Q-wave myocardial infarction (QWMI) and 19.5% of participants had target vessel revascularization (an invasive procedure required due to a stenosis in the same vessel treated in the study). This data supported MGuard's safety in the treatment of vein grafts and native coronary lesions.

Our 2007 study in Brazil included 30 patients who were candidates for a PCI (angioplasty) due to narrowing of a native coronary artery or a narrowed bypass graft. In all patients, the stent was successfully deployed with perfect blood flow parameters (the blood flow parameter is a measurement of how fast the blood flows in the arteries and the micro circulation system in the heart). Except for a single case of a major adverse cardiac event (3% of participants) that was non-QWMI, there were no major cardiac events at the time of the follow-up 30 days after the deployment of the MGuard.

The MAGICAL study, which was conducted in Poland, included 60 patients with STEMI. The purpose of the study was to evaluate the clinical performance of MGuard when used in STEMI patients where PCI is the standard treatment. Perfect blood flow in the target artery was achieved in 90% of patients treated. Perfect blood flow into the heart muscle was also achieved in 73% of patients and complete (>70%) restoration of electrocardiogram normality was achieved in 61.4% of patients. The total major adverse cardiac events rate during the six-month period followin