

InspireMD, Inc.  
Form 8-K  
November 05, 2014

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 4, 2014

**InspireMD, Inc.**

(Exact name of registrant as specified in its charter)

|  |                          |                                      |
|--|--------------------------|--------------------------------------|
| Delaware   | 001-35731                | 26-2123838                           |
| (State or other<br>jurisdiction<br>of incorporation) | (Commission File Number) | (IRS Employer<br>Identification No.) |

|  |            |
|--|------------|
| 321 Columbus Avenue                      |            |
| Boston, MA                               | 02116      |
| (Address of principal executive offices) | (Zip Code) |

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 1.01 Entry into a Material Definitive Agreement.**

On November 4, 2014, InspireMD, Inc. (the “Company”) entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with certain investors (collectively, the “Purchasers”) pursuant to which the Company has agreed to issue and sell to the Purchasers in a registered direct offering (the “Offering”) an aggregate of 6,261,846 shares of the Company’s common stock (collectively, the “Shares”) and warrants to purchase an aggregate of 3,130,923 shares of the Company’s common stock (collectively, the “Warrants” and the shares issuable upon exercise of the Warrants, collectively, the “Warrant Shares”), for aggregate expected gross proceeds of \$8,140,400. The Warrants have an exercise price of \$1.75 per share, and may not be exercised by the holder until the date that is six months after the closing date (the “Exercise Date”). The holder may exercise the warrants at any time after the Exercise Date until the date that is 42 months from the closing date, at which time any unexercised warrants will expire and cease to be exercisable. The Company expects that the Offering will close on or about November 7, 2014, subject to the satisfaction of customary closing conditions. The Company intends to use the net proceeds from the Offering to advance the development of its MGuard™ drug-eluting stent platform and develop the CGuard™ rapid exchange platform, commercially launch CGuard EPS, and for general corporate purposes.

The Shares, Warrants, and Warrant Shares will be issued pursuant to a prospectus supplement, which will be filed with the Securities and Exchange Commission in connection with a takedown from the Company’s shelf registration statement on Form S-3 (No. 333-191875), which became effective on November 27, 2013, and the base prospectus dated as of November 27, 2013 contained in such registration statement.

The form of the Securities Purchase Agreement and the form of Warrant are filed as Exhibits 10.1 and 10.2 hereto, respectively, and are incorporated herein by reference. The foregoing description of such documents and the transactions contemplated thereby is qualified in its entirety by reference to such exhibits.

**Item 2.02 Results of Operations and Financial Condition.**

The information provided in Item 8.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 2.02.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

## Item 8.01 Other Events.

### Business Updates

On November 4, 2014, the Company announced updates (the “Business Updates”) to the Business section of the Transition Report on Form 10-KT for the transition period from July 1, 2013 to December 31, 2013, as amended by Amendment No. 1 filed with the Securities and Exchange Commission on September 25, 2014 (the “Transition Report”) as set forth below. The Business Updates in this Current Report should be read in conjunction with the Transition Report, and the disclosures and information contained in the Business section of the Transition Report are not modified or updated in any way other than as set forth in the Business Updates. To the extent there is a conflict between the information contained in the Business Updates and the information contained in the Transition Report, you should rely on the information in the Business Updates. In addition, to the extent the Business Updates do not update any of the disclosures in the Transition Report, you can continue to rely on the Business section of the Transition Report, as modified by any subsequent filings made by us with the Securities and Exchange Commission.

### 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 are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

We market and sell our bare-metal based MGuard coronary products in the European Union, Southeast Asia, India, Latin America and Israel. In October 2007, our first generation MGuard coronary product 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 and, unless otherwise indicated, references to bare-metal MGuard coronary products are to both our initial stainless steel based MGuard coronary product and our more current cobalt-chromium based MGuard Prime. MGuard Prime 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 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.

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 we anticipate proceeding with animal testing in the fourth calendar quarter of 2014. We also intend to explore possible new applications of our technology in other vascular procedures and interventional medical specialties, specifically peripheral, neurovascular and renal procedures.

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

Since our formation, we have experienced net losses. We had a net loss of approximately \$13.5 million during the six months ended June 30, 2014, a net loss of approximately \$9.3 million during the six month transition period ended December 31, 2013, and a net loss of approximately \$29.3 million during the fiscal year ended June 30, 2013. Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing.

We are currently finalizing our financial results for the three months ended September 30, 2014. While complete financial information and operating data as of and for such period are not yet available, based on the information and data currently available, our management preliminarily estimates that for the three months ended September 30, 2014, our total revenue was \$273,000, compared to total revenue of \$193,000 for the three months ended June 30, 2014. Additionally, our management estimates that as of September 30, 2014, we had cash and cash equivalents of \$5.0 million, as compared to \$9.0 million at June 30, 2014. At September 30, 2014, management estimates negative cash flow from operations of \$14.3 million, as compared to \$7.8 million for the nine months ended September 30, 2013.

The preliminary financial data above have been prepared by, and is the responsibility of, our management. Our independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial data and does not express an opinion or any other form of assurance with respect thereto. Because the three months ended September 30, 2014 has recently ended, the financial information presented above for the three months ended September 30, 2014 reflects estimates based only upon preliminary information available to us as of the date of this Current Report and is not a comprehensive statement of our financial results for the three months ended September 30, 2014. Our financial statements and operating data as of and for the three months ended September 30, 2014 may differ from the preliminary unaudited financial information we have provided herein. Such differences may be material. Accordingly, you should not place undue reliance on these preliminary estimates. The estimates for the three months ended September 30, 2014 are not necessarily indicative of any future period and should be read together with "Risk Factors," "Special Note Regarding Forward-looking Statements,"

“Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes in our Transition Report.

## Recent Developments

On April 30, 2014, we initiated a voluntary field corrective action of our MGuard Prime to address the issue of stent retention following reports of MGuard Prime stent dislodgements. These reported dislodgements have primarily occurred during the preparation of the MGuard Prime, upon removal of the protective sleeve or during withdrawal of the MGuard Prime into the guide catheter. To address this problem, we subsequently modified our manufacturing process of MGuard Prime stents in order to improve stent retention and performance. On June 18, 2014, we received approval from the European regulatory agency to resume the manufacturing of the MGuard Prime stent with a modified stent securement process. We also received approval to modify and re-deploy existing MGuard Prime stents that have 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 October 2014 and intend to complete the full re-launch of MGuard Prime in 2015. The voluntary field corrective action had an adverse impact on both the commercial and clinical activities relating to the MGuard Prime in the three months ended June 30, 2014. For the three months ended June 30, 2014, our total revenue was \$193,000, as compared to total revenue of \$1.5 million for the three months ended March 31, 2014. As a result of the voluntary field corrective action, we also suspended enrollment in our MASTER II trial (defined below), which had been previously launched to support our investigational device exemption (IDE) application for MGuard Prime with the U.S. Food and Drug Administration, 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.

Notwithstanding the U.S. Food and Drug Administration's approval to re-commence enrollment of the MASTER II trial, in light of current market conditions moving toward the use of drug-eluting stents over bare-metal stents, we elected not to resume enrollment in the MASTER II trial. As a result of this change, the MASTER II trial will no longer be a U.S. Food and Drug registration trial. We intend to devote many of the resources originally planned for the MASTER II trial toward developing a drug-eluting stent coronary product incorporating our MicroNet mesh.

In September 2014, we announced the results of the first clinical trial of CGuard EPS, the CARENET (CARotid Embolic protection study using MicroNET) trial. The CARENET trial was a multi-specialty trial that assessed the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The CARENET trial recruited 30 patients and achieved its primary end point with 0 percent MACE (meaning no death, stroke or myocardial infarction) at 30 days. Additionally, as compared to published historical control groups of non-mesh covered carotid stents, the incidence of new ischemic lesions as assessed by diffusion-weighted magnetic resonance imaging after carotid artery stenting was reduced by almost 50 percent. The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than these historical control groups. The reduction in both the number of new ischemic lesions and the volume of those lesions indicates therapeutic benefits of the MicroNet technology in this patient cohort after 30 days, as compared to the historical control groups.

In October 2014, we launched a limited market release of and received first commercial orders for the CGuard EPS in certain European countries. The full launch of CGuard EPS is scheduled to occur in 2015, concurrently with the full launch of the rapid exchange delivery system for CGuard EPS.



## **“At the Market” Equity Offering Program**

Between October 23, 2013 and as of the date of this Current Report, we sold 948,000 shares of our common stock, at \$2.40 per share, pursuant to the at-the-market issuance sales agreement with MLV & Co. LLC. These sales resulted in net proceeds to us of approximately \$2.2 million. Prior to these sales, we had not made any sales under this “at-the-market” equity offering program, and, as the date of this Current Report, shares of our common stock having an aggregate value of approximately \$37.7 million remained available for sale under this offering program.

## **Our Industry**

### *Coronary*

According to Fact Sheet No. 310/updated May 2014 of the World Health Organization (“Fact Sheet No. 310”), approximately 7.4 million people worldwide died of ischemic heart disease in 2012. 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 Heath 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 the volume of stents in 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 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. 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 percutaneous coronary intervention 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.

## **Our Products and Applications**

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.

### ***MGuard Products— Coronary Applications***

Our MGuard coronary products combine a stent and MicroNet in a single device to be used in the treatment of coronary arterial disease.

***Bare-Metal Stent MGuard Products.*** Our MGuard EPS 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 biostable polymer mesh provide protection from dangerous embolic showers in patients experiencing 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 percutaneous coronary intervention (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 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 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. In October 2014, as noted above, we elected to discontinue enrollment in the MASTER II trial in its current form, 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 and expect to present the MASTER II trial 30-day data and the pooled data from the MASTER I trial and the MASTER II trial in the first calendar quarter of 2015.

We are establishing a multi-center, single-arm post-market registry of 700 patients with STEMI to collect post-CE mark trial clinical data on patients treated with MGuard Prime from 66 planned sites across Europe, which we refer to as our “eMASTER study.” We plan to evaluate the safety and efficacy of the MGuard Prime stent 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.

We are also in the process of obtaining ethics committee approvals in Poland, Germany and the U.K. in collaboration with St. Jude Medical, Inc. for a multi-center, randomized optical coherence tomography (OCT) study of up to 234 patients with STEMI to demonstrate the increased minimum flow area post-procedure with the use of MGuard Prime compared to the use of non-mesh bare-metal or drug-eluting stents. We will also be able to study OCT imaging of the thrombus protrusion or plaque protrusion in the stented coronary artery. If approved, patient enrollment is intended to begin in November 2014.

***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 total of two strategic partnerships with manufactures of FDA-approved or CE-marked drug-eluting stents and bring two viable drug-eluting stent products with our MicroNet mesh into the animal 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 launched 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, in Germany, Poland, Switzerland, Belgium, Italy and Spain. MicroNet is wrapped on an open cell stent platform which is designed to trap debris and emboli that can dislodge and travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect patients from plaque debris and blood clots breaking off and which can lead to life threatening strokes while keeping the stent flexible and easy to conform to the 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 design demonstrated better results over existing carotid stents when compared to historical data on these competitive 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 endarterectomy, given the superior embolic protection characteristics witnessed in coronary arterial disease applications in high risk patient populations. We intend that the embolic protection will result from the mesh sleeve, as it traps emboli at their source. In addition, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur immediately after a carotid stenting procedure and is often a 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 also shown that the majority of the incidents of embolic showers associated with carotid stenting occur immediately post-procedure.

The full launch of the CGuard EPS will occur concurrently with the rapid exchange delivery system for CGuard EPS. Since July 2014, we have been working with a medical device engineering and manufacturing vendor to develop a rapid exchange delivery system based on the market feedback requesting such delivery system for CGuard EPS. Stents are placed in the target site by a delivery system attached to a deflated balloon and a catheter at one end. Generally, a stent is mounted on the balloon, and the catheter is inserted into a blood vessel. Once the balloon reaches a blockage, it is inflated to open up the artery. Then the stent is advanced through the same vessel and positioned at the target site within the expanded artery. When the stent is positioned, the balloon is deflated and removed from the patient. An over-the-wire delivery system has two lumens and ports, one for the guide wire and the other for balloon inflation. The guide wire exists independent of the balloon, so two operators must perform the procedure. Our CGuard EPS is currently sold with the over-the-wire delivery system. A rapid exchange delivery system, on the other hand, has the guide wire that passes through the balloon and runs through the guiding catheter. It has one port and 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. The CGuard testers favored using a rapid exchange delivery system over over-the-wire delivery system with the CGuard stent. Our rapid exchange

delivery system is currently in design freeze (specifications are fixed and no further changes will be made), and we plan to submit our rapid exchange delivery system for CE mark approval at the end of 2014. Because the rapid exchange delivery system is already being used at many catheterization laboratories, we believe that our rapid exchange delivery system may receive the CE mark approval and be available for the full launch in early 2015. We plan to keep the focus of the full launch on the European Union and Latin America, primarily targeting high volume centers in core European markets. We intend to promote our CGuard EPS for use in a number of specialties that perform carotid artery stenting, including interventional cardiology, vascular surgery, interventional neuroradiology and interventional radiology. The full launch of our CGuard EPS will not include the U.S. We are preparing the trial protocol for a clinical trial in the U.S. involving CGuard EPS with the rapid delivery exchange system and planning to schedule pre-submission guidance meetings with the U.S. Food and Drug Administration to discuss a possible IDE application.



**PVGuard — Peripheral Applications**

We intend to develop our MicroNet mesh sleeve and a self-expandable stent for use in peripheral 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.*, “CQ1-2014” means January 1, 2014 through March 31, 2014). While we may seek approval from the U.S. Food and Drug Administration for our products in the future, we have not yet determined estimated timelines for any of our products. 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 uncertain.

| <b>Product</b>                             | <b>Indication</b> | <b>Start Development</b> | <b>CE Mark</b>   | <b>European Union Sales</b>        | <b>FDA Approval</b> | <b>U.S. Sales</b> |
|--|-------------------|--------------------------|------------------|------------------------------------|---------------------|-------------------|
| MGuard Coronary (bare-metal stent)         | Bypass/ Coronary  | 2005                     | Oct. 2007        | CQ1-2008                           | To be determined    | To be determined  |
| Drug-Eluting MicroNet (drug-eluting stent) | Bypass/ Coronary  | CQ1-2014                 | To be determined | To be determined                   | To be determined    | To be determined  |
| CGuard Carotid                             | Carotid Arteries  | CQ1-2011                 | Mar. 2013        | Oct. 2014 (limited market release) | To be determined    | To be determined  |



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

## **Growth Strategy**

Our primary business objective is to utilize our proprietary technology to become the industry standard for treatment of complex cardiovascular disease. We are pursuing the following business strategies in order to achieve this objective.

**Successfully commercialize CGuard EPS.** We have launched limited market release of CGuard through direct sales organization in select European countries. The initial commercial phase of our launch will be through our direct sales team in Europe and is expected to focus on high volume, key opinion leaders in the carotid space. By the time we convert to full market release, we expect to have generated usage and a broader awareness of the CGuard in key European markets, as well as a fully developed the rapid exchange delivery system for CGuard EPS.

**Successfully develop and commercialize the next generation of drug-eluting stent incorporating MicroNet.** While we market our MGuard products with bare-metal stents, we are developing a drug-eluting stent that incorporates MicroNet and expect to proceed with the animal testing of the product with a CE-marked drug-eluting stent candidate. If successful, and if no CE mark trial is required due to the fact that each of MicroNet and the drug-eluting stent is CE-marked, this work is expected to lead to submission by us of a DES-MicroNet platform for CE mark approval in the second half of 2015. We intend to develop two strategic partnerships with manufactures of FDA-approved or CE-marked drug-eluting stents and bring two viable drug-eluting stent products with our MicroNet mesh into the animal testing phase.

**Grow our presence in existing and new markets for MGuard coronary products.** We have commercialized bare-metal based MGuard products in Europe, Russia, Asia and Latin America through our distributor network, and we are pursuing additional registrations and contracts in other countries such as Canada, Australia, South Korea and certain smaller countries in Latin America. We have completed the modification of our stent securement process on inventory and are back to full commercial activities in direct markets in Western Europe and sales are under way, and we believe that the eMASTER study will reinforce this positive momentum. We intend to complete the full re-launch of MGuard Prime in 2015, and we have implemented a hybrid sales strategy with direct sales representatives in key European markets to support the full re-launch. We intend to re-evaluate our commercialization strategies for MGuard coronary products in the U.S. and Japan in the future following future development of the DES-MicroNet product and future clinical trial results.

**Continue to leverage 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 technology to address imminent market needs for new product innovations to significantly improve patients' care. We continue to broadly develop and file intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease, neurovascular disease, renal artery disease, and bifurcation disease.

**We work closely with leading physicians to evaluate and ensure the efficacy and safety of our products.** Some of these prominent physicians serve on our Scientific Advisory Board, which is our advisory committee that advises our board of directors and advises and participates in the operation of our clinical trials. These physicians have and will continue to generate and publish scientific data on the use of our products, and to present their findings at various key clinical conferences.

**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 MGuard, DES with MicroNet, CGuard EPS and other potential products that are based on our MicroNet technology. We are in discussions with multiple potential partners and may enter into an arrangement to pursue further development and commercialization of these products.

**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. Twelve separate patent applications have been filed in the U.S. and corresponding patent applications 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 technology 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.

## Intellectual Property

### *Patents*

We have filed twelve patent applications that are pending in the U.S. covering aspects of our MGuard and CGuard technology. We have filed corresponding patent applications in Canada, China, Europe, Israel, India and South Africa, for an aggregate total of 40 patents and pending applications. These patent rights are directed to cover percutaneous therapy, knitted stent jackets, stent and filter assemblies, *in vivo* filter assembly, optimized stent jackets, stent apparatuses for treatment via body lumens and methods of use, stent apparatuses for treatment via body lumens and methods of manufacture and use, and stent apparatuses for treatment of body lumens, among others. 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. On October 27, 2010, our patent application pertaining to “Stent Apparatus for Treatment via Body Lumens and Method of Use,” South African patent application 2007/10751, was issued as South African Patent No. 2007/10751. On October 25, 2011, our patent application pertaining to “In Vivo Filter Assembly,” U.S. Patent Application 11/582,354, was issued as U.S. Patent 8,043,323. On June 13, 2012, our patent application pertaining to “Filter Assemblies,” Chinese Patent Application No. 200780046659.9, was issued as Chinese Patent No. ZL200780046659.9. On September 26, 2012, our patent application pertaining to “Bifurcated Stent Assemblies,” Chinese Patent Application No. 200780046676.2, was issued as Chinese Patent No. ZL200780046676.2. On October 10, 2012, our patent application pertaining to “Knitted Stent Jackets,” Chinese Patent Application No. 200780046697.4, was issued as Chinese Patent No. ZL200780046697.4. On January 2, 2013, our patent application pertaining to “Optimized Stent Jacket,” Chinese Patent Application No. 200780043259.2, was issued as Chinese Patent No. ZL200780043259.2. We have also had Israeli Patent No. 198189 entitled “Filter Assemblies” issued March 27, 2014, and Patent No. 198190, entitled “Knitted Stent Jackets” issued Feb. 1, 2014, and Canadian Patent No. 2609687 entitled “Stent Apparatuses For Treatment Via Body Lumens” issued April 22, 2014. We believe one or more 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.

### *Trademarks*

We use the InspireMD® and MGuard® trademarks in connection with our products. We have registered these trademarks in Europe. The trademarks are renewable indefinitely, so long as we continue to use the mark in Europe and make the appropriate filings when required. We also have a registration for the MNP Micronet Protection Logo in Europe. We have also applied to register the names MicroNet™, Carenet™, MGuard™ and MGuard Prime™ as trademarks in the U.S., and we also own or have rights to various trademarks, trade names, and service marks including the following: CGuard™, PVGuard™, NGuard™, and RGuard™.

## **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. The bare-metal stent and the drug-eluting stent markets in the U.S. and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, and Medtronic, Inc. The carotid stent market in the U.S. and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd., and Cordis Corporation. Gore Medical and Terumo produce mesh-covered carotid stents. 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 channels that are more effective than ours. Due to ongoing consolidation in the industry, there are high barriers to entry for small manufacturers in both the European and the U.S. markets. However, we believe that the European market is somewhat more fragmented, and small competitors appear able to gain market share with greater ease.

In the future, we believe that physicians will look to next-generation stent technology to compete with existing therapies. These new technologies will likely 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 in the future as the portfolio of available stent technologies rapidly increases. As the market moves towards next-generation stenting technologies, minimally invasive procedures should become more effective, driving the growth of the market in the future. We plan to continue our research and development efforts in order to be at the forefront of the acute myocardial infarction solutions.

According to the MEDTECH OUTLOOK, the worldwide stent market is dominated by three major players, with a combined total market share of approximately 92%. Within the bare-metal stent market and drug-eluting stent market, the top three companies have approximately 71% and 97% of the market share, respectively. These three companies are Abbott Laboratories, Boston Scientific Corporation and Medtronic, Inc. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to the further growth of our products 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.

In addition to the challenges from our competitors, we face challenges related specifically to our products. None of our products is currently approved by the U.S. Food and Drug Administration. Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MicroNet products will be expensive and will require the enrollment of a large number of patients. Suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Furthermore, our rights to our intellectual property with respect to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MicroNet products based on one or more of these patents, and/or will allege misappropriation of their proprietary confidential information or other intellectual property.

## **Manufacturing and Suppliers**

We manufacture our stainless steel stents through a combination of outsourcing and assembly at our own facility. Third parties in Germany manufacture the base stent and catheter materials, and we add our proprietary mesh sleeve to the stent. Our current exclusive product supplier is QualiMed Innovative Medizinprodukte GmbH. QualiMed Innovative Medizinprodukte GmbH is a specialized German stent manufacturer that electro polishes and crimps the stent onto a balloon catheter that creates the base for our stainless steel MGuard stents. QualiMed Innovative Medizinprodukte GmbH has agreed to take responsibility for verifying and validating the entire stent system by performing the necessary bench test and biocompatibility testing. During the production process, QualiMed

Innovative Medizinprodukte GmbH is responsible for integrating the mesh covered stent with the delivery system, sterilization, packaging and labeling. Our manufacturing agreement with QualiMed Innovative Medizinprodukte GmbH expires in September 2017, unless earlier terminated by either party in the event of breach of material terms of the agreement, liquidation of the other party, our failure to receive requested products for more than 60 days, a substantiated intellectual property claim is brought against the other party or the development agreement between the parties is terminated. The manufacturing agreement provides for a rebate program that rewards us for increases in sales of our products.



The polymer fiber for MicroNet is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications.

Natec Medical Ltd. supplies us with catheters that help create the base for our MGuard stents. Our agreement with Natec Medical Ltd., which may be terminated by either party upon six months' notice, calls for non-binding minimum orders and discounted catheters upon reaching certain purchasing thresholds.

Creganna-Tactx Medical, Ireland supplies us with catheters for CGuard EPS.

Our MGuard Prime cobalt-chromium stent was designed by Svelte Medical Systems Inc. We have an agreement with Svelte Medical Systems Inc. that grants us a non-exclusive, worldwide license for production and use of the MGuard Prime cobalt-chromium stent for the life of the stent's patent, subject to the earlier termination of the agreement upon the bankruptcy of either party or the uncured default by either party under any material provision of the agreement. Our royalty payments to Svelte Medical Systems Inc. are determined by the sales volume of MGuard Prime stents. Until October 20, 2012, we paid a royalty of 7% for all product sales outside of the U.S. and, for products sales within the U.S., a rate of 7% for the first \$10.0 million of sales and a rate of 10% for all sales exceeding \$10.0 million. We also shared with Svelte Medical Systems Inc. in the cost of obtaining the CE mark approval, with its costs not to exceed \$85,000, and the cost of obtaining U.S. Food and Drug Administration approval, with its costs not to exceed \$200,000. On October 20, 2012, we amended our agreement with Svelte Medical Systems Inc., pursuant to which Svelte Medical Systems Inc. reduced the royalty rate to 2.9% of all net sales both inside and outside the U.S. in exchange for (i) us waiving the \$85,000 in regulatory fees for the CE mark that were owed to us by Svelte Medical Systems Inc., (ii) us making full payment of royalties in the amount of \$205,587 due to Svelte Medical Systems, Inc. as of September 30, 2012, and (iii) \$1,763,000, payable in 215,000 shares of our common stock (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012), that were valued at the closing price of our common stock on October 19, 2012 of \$8.20 per share (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012). On August 22, 2013, we further amended our agreement with Svelte Medical Systems Inc., pursuant to which (i) we agreed to pay Svelte Medical Systems Inc. an advanced payment of \$192,000, representing a royalty rate of 2.0% of all net sales for the period from July 1, 2013 to June 30, 2015, assuming net sales of \$1.2 million per quarter, (ii) we agreed to pay a royalty rate of 2.5% on any net sales exceeding \$10.56 million for the period from July 1, 2013 to June 30, 2015 and (iii) the royalty rate was increased to 2.9% of all net sales beginning July 1, 2015. We have mutual indemnification obligations with Svelte Medical Systems Inc. for any damages suffered as a result of third party actions based upon breaches of representations and warranties or the failure to perform certain covenants in the license agreement, and Svelte Medical Systems Inc. will also indemnify us for any damages suffered as a result of third party actions based upon intellectual property or design claims against the MGuard Prime cobalt-chromium stent.

Our MGuard Prime cobalt-chromium stent and our CGuard carotid stents are being manufactured and supplied by MeKo Laserstrahl-Materialbearbeitung. Our agreement with MeKo Laserstrahl-Materialbearbeitung for the production of electro polished L605 bare-metal stents for MGuard Prime and CGuard EPS is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for MGuard Prime and CGuard EPS, including knitting and securing the sleeve to the stent and the crimping of the sleeve stent on to a balloon catheter, is done at our Israel manufacturing site. Once MGuard Prime and CGuard EPS have been assembled, they are sent for sterilization in Germany and then back to Israel for final packaging.

Drug-eluting stents for our DES-MicroNet product will be supplied by existing drug-eluting stent manufacturers. We plan to develop two strategic partnerships with drug-eluting stent manufacturers who would supply FDA-approved or CE-marked stents.

Each MGuard stent is manufactured from two main components, the stent and the mesh polymer. The stent is made out of stainless steel or cobalt chromium. Both of these materials are readily available and we acquire them in the open market. The mesh is made from polyethylene terephthalate. This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications

A CGuard EPS consists of a CGuard stent and the delivery system. Each CGuard stent is manufactured from two main components, a self-expanding stent and the mesh polymer. The stent is made out of nitinol. This material is readily available and we acquire it in the open market. The mesh is made from polyethylene terephthalate. We have pending patent rights that cover the proposed CGuard stent with mesh. This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. The delivery system for CGuard is made out of polymer tubes we acquire from an original equipment manufacturer. In the event that our supplier can no longer supply this material, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications.

## **Corporate Information**

We were organized in the State of Delaware on February 29, 2008. Our principal executive offices are located at 321 Columbus Avenue, Boston, Massachusetts 02116. Our telephone number is (857) 453-6553. Our website address is [www.inspire-md.com](http://www.inspire-md.com). Information accessed through our website is not incorporated into this Current Report and is not a part of this Current Report.



## Risks Factors

The risk factors described in Part I, Item 1A, “Risk Factors” included in the Transition Report and the risk factors described in Part II, Item 1A, “Risk Factors” in subsequent Quarterly Reports on Form 10-Q are supplemented by the following additional risk factor:

*Our financial statements for the quarter ended June 30, 2014 contain an explanatory paragraph in the footnotes, as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.*

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Accordingly, the footnotes to our financial statements for the quarter ended June 30, 2014 include an explanatory paragraph as to our potential inability to continue as a going concern. Additionally, the doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

## Launch of a Public Offering

On November 4, 2014, the Company issued a press release announcing the Offering. A copy of the press release is filed as Exhibit 99.1 to this report. The Company is also filing its corporate presentation slides. These slides are filed as Exhibit 99.2 to this report. The slides are also available in the “Investor Relations—Presentations” section of the Company’s website, located at [www.inspire-md.com](http://www.inspire-md.com). Materials on the Company’s website are not part of or incorporated by reference into this Current Report on Form 8-K.

## Item 9.01 Financial Statements and Exhibits.

(d)

Exhibits

| <b>Exhibit Number</b> | <b>Description</b>                    |
|-----------------------|---------------------------------------|
| 10.1                  | Form of Securities Purchase Agreement |
| 10.2                  | Form of Warrant                       |
| 99.1                  | Press Release dated November 4, 2014  |

99.2 Slide Presentation of InspireMD, Inc. dated October 2014

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**InspireMD, Inc.**

Date: November 5, 2014 By: /s/ Craig Shore  
Name: Craig Shore  
Title: Chief Financial Officer