InspireMD, Inc. Form 424B5 March 03, 2015

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This preliminary prospectus supplement relates to an effective registration statement under the Securities Act of 1933, but the information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MARCH 3, 2015** 

PRELIMINARY PROSPECTUS SUPPLEMENT (To Prospectus dated November 27, 2013)

InspireMD, Inc.

**Shares of Common Stock** 

Warrants to Purchase Shares of Common Stock

**Shares of Common Stock Underlying Warrants** 

We are offering up to shares of our common stock and warrants to purchase up to shares of our common stock (and the shares of common stock issuable from time to time upon exercise of these warrants). Each share of common stock we sell in this offering will be accompanied by a warrant to purchase one share of common stock at an exercise price per warrant of \$ per share. Each share of common stock and accompanying warrant will be sold at a negotiated price of \$ . The shares of common stock and warrants will be issued separately but can only be purchased together in this offering.

Our common stock is traded on the NYSE MKT under the symbol "NSPR." We do not intend to apply for any listing of the warrants on any securities exchange and we do not expect that the warrants will be quoted on the NYSE MKT. On March 2, 2015, the last reported sale price of our common stock as reported on the NYSE MKT was \$0.60 per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page S-12 of this prospectus supplement and page 6 of the accompanying prospectus.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive sole bookrunner, or exclusive lead placement agent ("lead placement agent"), and Dawson James Securities, Inc. as our co-placement agent ("co-placement agent" and, collectively with the lead placement agent, the "placement agents") in connection with the shares of common stock and warrants offered by this prospectus supplement. The placement agents have agreed to use their reasonable best efforts to arrange for the sale of the common stock and warrants offered by this prospectus supplement. The placement agents are not purchasing or selling any of the shares of common stock or warrants we are offering and the placement agents are not required to arrange the purchase or sale of any specific number of shares or dollar amount. We have agreed to pay to the placement agents the placement agent fees set forth in the table below, which assumes that we sell all of the common stock and warrants we are offering.

	Per Share(1)	Total
Public offering price	\$	\$
Placement agent's fees (2)	\$	\$
Proceeds, before expenses, to us	\$	\$

- (1) Per share price represents the offering price for one share of common stock and a warrant to purchase one share of common stock.
- (2) We have agreed to reimburse the lead placement agent for certain offering-related expenses. See "Plan of Distribution."

We have agreed to pay to the placement agents a placement agent fee equal to 8% of the aggregate gross proceeds in this offering. We have also agreed to reimburse the lead placement agent for its expenses in connection with this offering in an amount equal to 1% of the aggregate gross proceeds in this offering. We estimate total expenses of this offering, excluding the placement agent fees, will be approximately \$ . Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See "Plan of Distribution" beginning on page S-39 of this prospectus supplement for more information on this offering and the placement agent arrangements.

Certain of our directors and executive officers and their affiliated entities, have indicated an interest in purchasing an aggregate of up to approximately \$1,250,000 in shares of our common stock and warrants in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these directors and executive officers may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock and warrants is expected to be made on or about March , 2015, subject to customary closing conditions.

# H.C. WAINWRIGHT & CO.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus supplement is March , 2015.

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement or the accompanying prospectus. You must not rely on any unauthorized information or representations. This prospectus supplement and the accompanying prospectus are an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of their respective dates.

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission utilizing a "shelf" registration process. This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the placement agents have not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein or therein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled "Where you can find more information" and "Incorporation of certain information by reference" in this prospectus supplement and in the accompanying prospectus, respectively.

We are offering to sell, and seeking offers to buy, the securities offered by this prospectus supplement only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the securities offered by this prospectus supplement in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to,

the offering of the common stock and warrants and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

All references in this prospectus supplement and the accompanying prospectus to "InspireMD," the "Company," "we," "us," "our," or similar references refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries taken as a whole, except where the context otherwise requires or as otherwise indicated.

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#### PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference herein and therein. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including "Risk Factors," the financial statements, and related notes, and the other information incorporated by reference herein and therein.

#### 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).

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 prospectus supplement, 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 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.

Since our formation, we have experienced net losses. We had a net loss of approximately \$20.3 million during the nine months ended September 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.

# **Recent Developments**

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.

As a result of the voluntary field corrective action, we 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 EPS 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 the CGuard EPS will occur concurrently with the introduction of the new rapid exchange delivery system for CGuard EPS. Our rapid exchange delivery system 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.

During the fourth quarter of 2014, we began implementing a focused spending plan. The plan included reducing the focus of clinical and development expenses related to our bare metal stent product and increasing the focus on our drug eluting stent product. Prior to the fourth quarter of 2014, a large portion of our organization was supporting our MASTER II trial, in which we determined not to resume enrollment, and instead allocated resources to drug eluting stents and the CGuard platform.

During the first quarter of 2015, the board of director approved implementing another cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only the drug eluting stent product; (iii) limiting sales and marketing expenses to only those related to the CGuard EPS stent launch; and (iv) reducing across the board all other expenses (conferences, travel, promotional

expenses, executive cash salaries, director cash fees, etc.). Prior to the cost reduction plan, a large portion of our organization was supporting clinical trials and promotional activities related to our bare metal stent platform. We decided to discontinue all work and promotion (such as conferences, clinical studies, and some sales activities) related to the bare metal platform. This decision allowed us to eliminate certain positions that related only to these activities. In addition, we dramatically cut all expenses not directly related to the CGuard launch and drug eluting platform development.

In addition, to reduce the usage of cash, on January 5, 2015, we amended our employment agreements with Alan Milinazzo and James Barry, Ph.D. to provide that, for a limited period of time to be mutually agreed to by us and each of Mr. Milinazzo and Dr. Barry, each of Mr. Milinazzo and Dr. Barry shall receive 50% of his base salary in cash payments, with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock, payable and granted in equal installments in accordance with our normal payroll practices. On the same date, our compensation committee amended its compensation policy for directors to provide that effective as of July 1, 2014, each director would forego any cash compensation in exchange for such number of immediately vested 10 year stock options having a Black-Scholes value equal to the cash compensation otherwise due to such director under our current director compensation policies. On February 22, 2015, Dr. Barry's employment agreement was further amended to provide that the payment arrangement described above would continue until the earlier of (i) September 30, 2015 and (ii) our raising an aggregate of \$5 million from investors.

## "At the Market" Equity Offering Program

Between October 23, 2013 and as of the date of this prospectus supplement, 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 prospectus supplement, shares of our common stock having an aggregate value of approximately \$37.7 million remained available for sale under this offering program. Our securities purchase agreement with purchasers of shares of our common stock and warrants to purchase our common stock, dated November 4, 2014, entered into in connection with the registered direct offering described below, prohibits us from issuing and selling additional shares of our common stock under this "at-the-market" equity offering program until November 7, 2016.

# **Registered Direct Offering**

On November 7, 2014, we sold 6,261,846 shares of our common stock and warrants to purchase 3,130,923 shares of our common stock in a registered direct offering. The common stock was sold at a negotiated purchase price of \$1.30 per share, and each purchaser received a warrant to purchase one-half of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months after the date of issuance and have a term of exercise of 42 months after the date of issuance and an exercise price of \$1.75. This offering resulted in net proceeds to us of approximately \$7.4 million after deducting placement agent fees

# **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 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 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 though 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 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 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 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 International Conference for Innovations in Cardiovascular Systems ("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 EPS 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.

Product	Indication	CE Mark	European Union Sales	FDA Approval(1)	U.S. Sales
MGuard stent	Bypass/ Coronary	Oct. 2007	CQ1-2008	To be determined	To be determined
(bare-metal stent)	Coronary			determined	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

<sup>(1)</sup> We anticipate that the 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 acute coronary syndromes and to provide a superior solution to the common acute problems caused by current stenting procedures, such as restenosis, embolic showers and late thrombosis. We are pursuing the following business strategies 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 in vivo pre-clinical 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 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.

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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 EPS 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 fourteen 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 42 patents and pending applications including two issued U.S. patents. 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, 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. U.S. Patent Application No. 11/797,168, filed May 1, 2007, was issued as U.S. Patent No. 8,961,586 on February 24, 2015. We also believe that 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<sup>®</sup> and MGuard<sup>®</sup> trademarks in connection with our products. We have registered these trademarks in the European Union. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have a registration for the MNP Micronet Protection Logo in the European Union. We have also applied to register the names MicroNet<sup>TM</sup>, Carenet<sup>TM</sup>, CGuard<sup>TM</sup> and MGuard Prime<sup>TM</sup> as trademarks in the U.S. and the names Carenet<sup>TM</sup>, CGuard<sup>TM</sup> and MGuard Prime<sup>TM</sup> in the European Union. We also use and may have common law rights to various trademarks, trade names, and service marks including the following: PVGuard<sup>TM</sup>, NGuard<sup>TM</sup>, and RGuard<sup>TM</sup>.

# 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 over the wire catheters for CGuard EPS.

Vention Medical Advance Components, Boston, Massachusetts supplies us with rapid exchange catheters for CGuard EPS.

Our MGuard Prime EPS 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 EPS 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 EPS 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 Syelte 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 EPS cobalt-chromium stent.

Our MGuard Prime EPS 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 EPS and CGuard EPS is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for MGuard Prime EPS 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 EPS 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 U.S. Food and Drug Administration-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-expending 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. Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus supplement.

#### THE OFFERING

Issuer

InspireMD, Inc.

Securities offered by us in this offering

shares of our common stock, par value \$0.0001 per share

Warrants to purchase up to shares of common stock, with an exercise price equal to \$ per full share.

shares of common stock issuable upon exercise of the warrants.

Offering price

\$ per share of common stock and accompanying warrant to purchase one share of our common stock.

Common stock outstanding immediately before this offering

43,786,411 shares

Common stock outstanding

shares (assuming the sale of all shares covered by this prospectus and assuming no immediately after this exercise of any of the warrants offered hereby)

Use of proceeds

offering

We estimate that our net proceeds from this offering (based on a public offering price of per share) will be approximately \$ million after deducting estimated placement agent fees and other estimated offering expenses payable by us (assuming the sale of all shares covered by this prospectus and assuming no exercise of any of the warrants offered hereby).

We plan to use the net proceeds of this offering to commercially launch CGuard EPS, conduct sales activities related to MGuard Prime EPS and advance the development of our pipeline. Any balance of the net proceeds will be used for general corporate purposes. See "Use of Proceeds."

Dividend policy

We have not declared or paid any cash or other dividends on our common stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future. See "Dividend Policy."

Risk factors

You should carefully read and consider the information beginning on page S-12 of this prospectus supplement and page 6 of the accompanying prospectus set forth under the headings "Risk Factors" and all other information set forth in this prospectus supplement, the accompanying prospectus, and the documents incorporated herein and therein by reference before deciding to invest in our common stock and warrants.

# NYSE MKT symbol for common stock

NSPR. The warrants will not be listed on the NYSE MKT or any other exchange or trading market. There is no established trading market for the warrants and we do not expect any such trading market to develop.

The number of shares to be outstanding immediately before and immediately after this offering is based on 43,786,411 shares of our common stock outstanding as of March 2, 2015 and excludes as of that date:

- 1,953,712 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of \$7.20 per share;
- .637,500 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of \$6.00 per share;
- 659,091 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of \$3.00 per share;
- . 168,351 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of \$2.97 per share;
- 3,130,923 shares of common stock issuable upon the exercise of currently outstanding warrants to purchase one-half of one share of common stock with an exercise price for two warrants of \$1.75 per full share;
- 7,113,297 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from \$0.0001 to \$10.40 and having a weighted average exercise price of \$3.28 per share;
- ·84,534 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan; and
- · 362,201 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

Certain of our directors and executive officers and their affiliated entities, have indicated an interest in purchasing an aggregate of up to approximately \$1,250,000 in shares of our common stock and warrants in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these directors and executive officers may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

#### RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. Please also read carefully the section below entitled "Special Note Regarding Forward-Looking Statements."

#### Risks Related to Our Business

We have a history of net losses and may experience future losses.

To date, we have experienced net losses. A substantial portion of the expenses associated with our manufacturing facilities are fixed in nature (i.e., depreciation) and will reduce our operating margin until such time, if ever, as we are able to increase utilization of our capacity through increased sales of our products. The clinical trials necessary to support our anticipated growth will be expensive and lengthy. In addition, our strategic plan will require a significant investment in clinical trials, product development and sales and marketing programs, which may not result in the accelerated revenue growth that we anticipate. Because we expect to continue incurring negative cash flows from operations, there can be no assurance that we will ever generate sufficient revenues to