InspireMD, Inc.
Form 424B5
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PRELIMINARY PROSPECTUS SUPPLEMENT
(To Prospectus dated November 27, 2013)

InspireMD, Inc.

1,900,000 Shares of Common Stock
Warrants to Purchase 950,000 Shares of Common Stock
950,000 Shares of Common Stock Underlying Warrants

We are offering 1,900,000 shares of our common stock and warrants to purchase up to 950,000 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 half of one share of common stock at an exercise price for two warrants of $0.59 per full share. Each share of common stock and accompanying warrant is being offered at a price of $0.59. The shares of common stock and warrants will be issued separately but can only be purchased together in this offering. We are also offering warrants to purchase up to 95,000 shares of our common stock (and the shares of common stock issuable from time to time upon exercise of these warrants) issued to the underwriter or its designee.

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 14, 2016, the last reported sale price of our common stock as reported on the NYSE MKT was $0.84 per share.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-10 of this prospectus supplement and page 6 of the accompanying prospectus.

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.

	Per Share(1)	Total
Public offering price	$ 0.59	$1,121,000
Underwriting discount (2)	$ 0.0472	$89,680
Proceeds, before expenses, to us	$ 0.5428	$1,031,320

(1) Per share price represents the offering price for one share of common stock and a warrant to purchase one half of one share of common stock.

(2) In addition, we have agreed to reimburse the underwriter for certain offering-related expenses and to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 5% of the shares of common stock sold in this offering, which warrants and underlying common stock are also being offered pursuant to this prospectus supplement. See “Underwriting” for more information.

Dawson James Securities, Inc., its officers and its registered representatives may participate in this offering on the same terms and conditions as the investors participating in this offering.

Concurrently with the closing of this offering, certain of our directors and executive officers have agreed to purchase in a private placement an aggregate amount of approximately $600,000 of our common stock and warrants on the same terms as this offering.

The underwriter expects to deliver the shares of common stock and warrants on or about March 21, 2016.

As of March 14, 2016, the aggregate market value of our outstanding common stock held by non-affiliates was $6,145,444, based on 7,794,075 shares of our common stock outstanding on March 14, 2016, of which 6,983,459 shares were held by non-affiliates, and a price of $0.88 per share, the closing price of our common stock on March 9, 2016. During the 12 calendar months prior to and including the date of this prospectus supplement, we have offered securities with an aggregate market value of $2,040,600 pursuant to General Instruction I.B.6 of Form S-3.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus supplement is March 16, 2016.

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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 underwriter has 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.

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 vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines our MicroNet mesh and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of the CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize the CGuard EPS in Argentina and Columbia.

Our MGuard™ coronary product, MGuard Prime Embolic Protection System ("MGuard Prime EPS"), is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). We market and sell MGuard Prime EPS, a bare-metal cobalt-chromium based stent, for the treatment of coronary disease in the European Union. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product. Due to limited resources, though, our efforts to date have been limited to incorporating our MicroNet in-house onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

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

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

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard™ EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

Financial Update

While we have not finalized our full financial results for the fiscal year ended December 31, 2015, our total revenue for the twelve months ended December 31, 2015 was $2.3 million and our net loss was approximately $15.6 million. In addition, we had approximately $3.3 million of cash, cash equivalents and short-term investments as of December 31, 2015. These financial results are an estimate only, have not been audited and are subject to change upon completion of the audit of our financial statements as of and for the year ended December 31, 2015. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2015. The preliminary financial data included in this prospectus supplement has been prepared by, and is the responsibility of management. Kesselman and Kesselman, our independent registered public accounting firm, a member firm of PricewaterhouseCoopers International Limited, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial data. Accordingly, it does not express an opinion or any other form of assurance with respect thereto. Our actual results for the period ended December 31, 2015 may not be available until after this offering is completed. There can be no assurance that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within our control. For additional information regarding various risks and uncertainties, see “Risk Factors” and “Special Note Regarding Forward-Looking Statements” elsewhere in this prospectus supplement.

Since our formation, we have experienced net losses. We had a net loss of approximately $12.7 million during the nine months ended September 30, 2015, a net loss of approximately $25 million during the fiscal year ended December 31, 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 as a going concern at the same level we are currently performing. We anticipate that we will have a going concern paragraph from our independent registered public accounting firm for the year ended December 31, 2015.

Recent Developments

Effective as of October 1, 2015, we amended our certificate of incorporation in order to (i) effectuate a one-for-ten reverse stock split of our outstanding shares of common stock and (ii) reduce the number of authorized shares of our common stock from 125,000,000 to 50,000,000. All share and related option and warrant information presented in this prospectus supplement have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

Our Industry

Carotid

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

The potential 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 (*source: JMP Securities 2014 and Cowen 2014)*. 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. We believe that the use of a stent with an embolic protection system should increase the number of patients being treated since it

would avoid the need for complex surgery.

Coronary

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

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

Neurovascular

The neurovascular market focuses on catheter-delivered products used to treat strokes that already happened or unruptured brain aneurysms that could lead to strokes. In the latter case, coils are wound into blood vessel bulges to block blood flow entering the aneurysms to prevent the aneurysms from rupturing. Endovascular treatment of arterial aneurysm has evolved substantially over the past two decades, transitioning from an investigational therapy into routine clinical practice and ultimately emerging as the treatment of choice for many lesions *(source: Medtech Ventures 2009, Aneurysm Flow Modulating Device Market).* We believe that the market for aneurysm flow modulating devices is still in the embryonic stage with windows of opportunities for early entrance. The global market for the endovascular treatment of cerebral aneurysms, which currently stands at $980 million, is expected to reach $1.4 billion by 2020, at a compound average annual growth rate of 5% per year (*source: Medtech Ventures, Endovascular Cerebral Aneurysm Repair Market, October 2013*).

The neurovascular market includes over-the-wire, flow-guided microcatheters, guiding catheters, coil and liquid embolics, neurovascular stents and flow diversion stents. According to iData Research, the market is expected to be driven by the conversion from surgical procedures to endovascular techniques in the treatment of aneurysms and arteriovenous malformations.

Our Products

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

MicroNet

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

CGuard™ – Carotid Applications

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

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

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

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical endarterectomy, given the superior embolic protection characteristics provided by the MicroNet. We believe the MicroNet will provide acute embolic protection at the time of the procedure, but more importantly, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur up to 48 hours post-procedure. It is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain. Schofer, et al. (“Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging,” *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

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

In September 2015, we announced full market launch of the CGuard EPS by our distribution partner, Penumbra, Inc., in 17 CE marked countries in Europe. In October 2015, we received regulatory approval to commercialize the CGuard EPS in Argentina and Columbia. We are currently preparing materials required to conduct a clinical trial in the United States. Once complete, we plan to request a pre-submission guidance meeting with the U.S. Food and Drug Administration.

MGuard Products– Coronary Applications

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

During the fourth quarter of 2014, due to a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, we decided to curtail developing and promoting our bare-metal stent platform and instead focus on the development of a drug-eluting stent product.

Drug-Eluting Stent MicroNet Product Candidate. During 2015, we completed the second phase of development work for our MGuard DES™, pursuant to which we incorporated our MicroNet with a drug-eluting stent manufactured by a prospective partner. 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. However, due to our limited resources we have tabled further development of MGuard DES at this time.

NVGuard – Neurovascular

We are developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms to ultimately seal the aneurysms. Flow diversion is a growing market segment within the neurovascular medical device field. Current commercial flow diverters are highly flexible dense metal mesh tubes that

go across most types of cerebral aneurysms and divert the blood flow away from the aneurysm with the desired end result of sealing the aneurysm. The challenges with the current flow diverters are that they (i) are difficult to place given the high metal content in the device, which makes it more difficult to move the device through the delivery system due to resistance from the metal, and to subsequently accurately place it, (ii) need to be accurately placed to avoid crossing and blocking other cerebral vessels, which could cause additional damage by cutting off blood flow to sections of the brain, (iii) require chronic use of anti-thrombotic medications due to the amount of metal in the cerebral vasculature, which could cause thrombotic complications, and (iv) do not allow a physician to reaccess the aneurysm if the aneurysm does not seal, in which event the aneurysm may need to be treated with another therapy such as aneurysm coils, due to the tight metal mesh that will not allow other devices to pass through the flow diverter.

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

In addition to our plan to develop our own flow diverter, we are also evaluating the opportunity to partner with a device company that either has an existing flow diverter or is looking for an entry into the market.

Growth Strategy

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

- **Grow our presence in existing and new markets for CGuard EPS.** We have fully launched CGuard EPS in most European and Latin American countries, through a combination of distributor sales organizations as well as a partnership with Penumbra, Inc., a global interventional therapies company focused on the neuro and peripheral vascular specialties, to distribute CGuard EPS in Europe Europe in 17 CE marked countries. We are also pursuing additional registrations and contracts in other countries in Europe, Asia and Latin America.

- **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 protect 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 CGuard EPS and our NVGuard flow diverter, as well as future efforts with MGuard Prime EPS, MGuard DES, and other potential products that are based on our MicroNet technology.

- **Continue to protect and expand our portfolio of patents.** Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Twelve separate patent applications have been filed in the United States some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products, and may be useful for protecting our future 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.

- **Resume development and successfully commercialize the next generation of drug-eluting stent incorporating MicroNet.** While we have limited the focus of product development to carotid and neurovascular products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop a drug-eluting stent that incorporates MicroNet.

Competition

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

Carotid

The carotid stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), and Cordis Corporation. Gore Medical and Terumo Medical Corporation 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. However, we believe that the European market is somewhat fragmented, and, in our opinion, smaller competitors may be able to gain market share with greater flexibility.

Coronary

The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, and Medtronic, Inc. In 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.

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

Neurovascular

Stryker Corporation dominated the global interventional neurology market in 2014. The other key players in this market include Medtronic plc, Johnson & Johnson, Terumo Corporation, Penumbra, Inc., Abbott Laboratories, Merit Medical Systems, Inc., W. L. Gore & Associates, Inc., Microport Scientific Corporation, and Medikit Co., Ltd., among others. (*source: Markets and Markets 2015).*

Distributors

We currently have distribution agreements for our CE mark-approved MGuard and CGuard EPS products with medical product distributors based in Europe, the Middle East, Asia Pacific, Australia, South Africa and Latin America. We are currently in discussions with additional distribution companies in Europe, Asia, and Latin America.

Penumbra Distribution Agreement

On August 5, 2015, InspireMD, Ltd., our wholly owned subsidiary, entered into a distribution agreement with Penumbra, Inc., pursuant to which Penumbra, Inc. will act as the exclusive distributor of CGuard EPS in Austria, France, Sweden, Denmark, Norway, Finland, Estonia, Lithuania, Portugal, Switzerland and the United Kingdom and Ireland. The territory covered by the distribution agreement also includes non-exclusive rights to distribute CGuard EPS in Latvia, Belgium, the Netherlands, Luxembourg, Germany and Poland.

Under the terms of the distribution agreement, we will use all commercially reasonable efforts to obtain all required permits, licenses and other approvals necessary to import, market or sell the CGuard EPS in the territory covered by the distribution agreement. Within 60 days after receipt of all such required approvals in a given territory, Penumbra, Inc. shall place its initial stocking order for CGuard EPS, for which Penumbra, Inc. will pay one-half of the purchase price upon placing such order and the remainder of the purchase price 30 days after receipt of the CGuard products and our invoice for such CGuard EPS products. If, in our reasonable discretion, Penumbra, Inc. fails to order a sufficient quantity of CGuard EPS to successfully commercialize the CGuard EPS in the applicable territory, then we may reduce the territory covered by the distribution agreement upon providing 60 days' notice to Penumbra, Inc.

The distribution agreement requires Penumbra, Inc. to use commercially reasonable efforts to purchase CGuard EPS in certain minimum target amounts agreed to by the parties for the 2015 and 2016 calendar years. For all subsequent calendar years during the term of the distribution agreement, the parties will agree to the minimum annual purchase targets at least 30 days prior to the commencement of such calendar year, which shall be determined in good faith by mutual agreement, taking into account various relevant factors, such as the sales attained during the preceding calendar year and prevailing market conditions, among others. The parties fixed the initial prices to be paid by Penumbra, Inc. for CGuard EPS through December 31, 2015, which were subject to certain reductions for inventory shelf life and other adjustments negotiated by the parties.

The initial term of the distribution agreement ends on December 31, 2018, unless sooner terminated pursuant to the termination rights set forth therein. Either party may terminate the distribution agreement (i) without cause upon providing 60 days' notice to the other party, (ii) upon the other party's material breach of the distribution agreement, which is not cured 30 days after written notice thereof from the non-breaching party and (iii) immediately without notice upon the bankruptcy, insolvency, dissolution, assignment for the benefit of creditors or similar event with respect to the other party. We may also terminate the distribution agreement if it reasonably believes that Penumbra, Inc., or any party acting on its behalf, has violated the United States Foreign Corrupt Practices Act of 1977. In addition, if at any time during the term of the distribution agreement, Penumbra, Inc. distributes or offers for sale products that, in our reasonable judgment, compete with CGuard EPS, then we may terminate the distribution agreement or change the exclusive rights granted to non-exclusive rights upon providing 30 days' notice to Penumbra, Inc.

Pursuant to the distribution agreement, we are subject to customary covenants and other continuing regulatory, record-keeping and reporting obligations.

The distribution agreement also contains a limited three year warranty for CGuard EPS and other mutual confidentiality and indemnification obligations for us and Penumbra, Inc.

Current and future agreements with distributors stipulate that, while we are responsible for training, providing marketing guidance, marketing materials, and technical guidance, distributors will be responsible for carrying out local registration, sales and marketing activities. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. Under current agreements, distributors purchase stents from us at a fixed price. Our current agreements with distributors are generally for a term of approximately three years.

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	1,900,000 shares of our common stock, par value $0.0001 per share
	Warrants to purchase up to 950,000 shares of common stock with an exercise price for two warrants of $0.59 per full share, and warrants to purchase up to 95,000 shares of common stock issued to the underwriter or its designee with an exercise price of $0.7375 per share.
	1,045,000 shares of common stock issuable upon exercise of the warrants, including 95,000 shares of common stock issuable upon exercise of the warrants issued to the underwriter or its designees.
Offering price	$0.59 per share of common stock and accompanying warrant to purchase one half of one share of our common stock.
Common stock outstanding immediately before this offering	7,794,075 shares
Common stock outstanding immediately after this offering	9,694,075 shares (assuming no exercise of any of the warrants offered hereby)
Use of proceeds	We estimate that our net proceeds from this offering (based on a public offering price of $0.59 per share) will be approximately $868,820 after deducting the underwriting discount and estimated offering expenses payable by us (assuming no exercise of any of the warrants offered hereby).
	We plan to use the net proceeds of this offering to conduct sales activities related to CGuard™ EPS™ and MGuard Prime™ EPS. 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-10 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 7,794,075 shares of our common stock outstanding as of March 14, 2016 and excludes as of that date:

- 195,393 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $72.00 per share;
- 63,750 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $60.00 per share;
- 65,912 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $30.00 per share;
- 16,836 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $29.70 per share;
- 313,100 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 $17.50 per full share;
- 3,436,970 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $5.50 per share;
- 95,000 shares of common stock issuable upon the exercise of warrants that we have agreed to issue to the underwriter or its designees in this offering equal to 5% of the shares of common stock sold in this offering, at a price per share equal to 125% of the public offering price in this offering;
- 336,430 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.0001 to $84.00 and having a weighted average exercise price of $30.25 per share;
- 243,580 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan, 243,580 of which will be granted to Isaac Blech in connection with his appointment to our board of directors; and
- 673,261 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan, 536,420 of which will be granted to Isaac Blech in connection with his appointment to our board of directors.

Concurrently with the closing of this offering, certain of our directors and executive officers have agreed to purchase in a private placement an aggregate amount of approximately $600,000 of our common stock and warrants on the same terms as 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.

We have yet to establish any history of profitable operations. We expect to report a net loss of $15.6 million for the fiscal year ended December 31, 2015 and had a net loss of approximately $25 million during the fiscal year ended December 31, 2014. As of December 31, 2015, we had an accumulated deficit of $123 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

Our financial statements contain, and, notwithstanding our completion of this offering, the report of our independent registered public accounting firm is expected to contain, an explanatory paragraph 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, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, the footnotes to our financial statements for the three months ended September 30, 2015 include an explanatory paragraph as to our potential inability to continue as a going concern. 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. Further, notwithstanding our completion of this offering, we anticipate that we will have a going concern paragraph from our independent registered public accounting firm for the year ended December 31, 2015 when we file our annual financial statements for the fiscal year ended December 31, 2015.

We will need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests.

The net proceeds from this offering are expected to be sufficient to enable us to continue operations for only a short period of time. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital no later than the beginning of the second quarter of 2016, depending on the proceeds from this offering, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- developing CGuard EPS, MGuard DES, NVGuard and any additional products;
- pursuing growth opportunities, including more rapid expansion;
- making capital improvements to improve our infrastructure;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares. Further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

The voluntary field action of our MGuard Prime EPS we initiated in 2014 could continue to have a significant adverse impact on us.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

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 in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. We received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, and we began shipping products to new customers in our direct markets in Western Europe in late September 2014. We completed the full re-launch of MGuard Prime EPS in 2015, with the exception of Russia.

As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

- although we resumed manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, our suspension of shipments has and may continue to adversely impact revenue;

- we are more susceptible to claims such as product liability claims, distributor claims and class action lawsuits as a result of the reported product malfunction and voluntary field action, which could significantly increase our costs and may have a material adverse effect on our business, financial condition and results of operations;

- our decision to implement the voluntary field action and discontinue shipments, and any additional action related to such decision, may harm our reputation or the market's perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events, such as the MGuard Prime EPS stent dislodgements, have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation and financial results.

In addition to the foregoing, since we initiated our voluntary field action we have received a demand from one distributor that we refund approximately $160,000 in lieu of receiving refitted product and a demand from a second distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action, related costs and any third claims. We do not believe that these distributors are entitled to any compensation or refunds due to the voluntary field action and we intend to defend ourselves against any such claims, however, regarding the demand from the second distributor, we believe that a loss from any related future proceedings that could range from a minimal amount up to 1,075,000 Euros is reasonably possible. While we are disputing these claims, should an action be filed we could be forced to pay damages which could result in a material adverse effect on our business.

We expect to derive our revenue from sales of our Mguard Prime EPS and CGuard EPS stent products and other products we may develop, such as NVGuard. If we fail to generate revenue from these sources, our results of operations and the value of our business would be materially and adversely affected.

We expect our revenue to be generated from sales of our MGuard Prime EPS and CGuard EPS stent products and other products we may develop. Future sales of CGuard EPS will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. In addition, sales of MGuard Prime EPS have been hampered by weakened demand for bare metal stents, which may never improve, and we may not be successful in developing a drug-eluting stent product. In addition, there may be insufficient demand for other products we are seeking to develop, such as NVGuard. If we fail to generate expected revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Similarly, the ability to protect our trademark rights might be important to prevent third party counterfeiters from selling poor quality goods using our designated trademarks/trade names. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patent applications and patents may not provide us with commercially meaningful protection for our products or may not afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us now or in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our

stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States.

In addition, statutory differences in patentable subject matter depending on the jurisdiction may limit the protection we obtain on certain of the technologies we develop. The laws of some foreign jurisdictions do not offer the same protection to, or may make it more difficult to effect the enforcement of, proprietary rights as in the United States, risk that may be exacerbated if we move our manufacturing to certain countries in Asia. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights on any patents issued on pending patent applications, which may prompt adversaries in such litigation to challenge the validity, scope, ownership, or enforceability of our patents. Third parties can sometimes bring challenges against a patent holder to resolve these issues, as well. If a court decides that any such patents are not valid, not enforceable, not wholly owned by us, or are of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patent rights are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor do they provide us with freedom to operate unimpeded by the patent and other intellectual property rights of others that may cover our products. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

If our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our MGuard Prime EPS and CGuard EPS products at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard Prime EPS or CGuard EPS stents until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard Prime EPS or CGuard EPS stents to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

Additionally, any damage to or destruction of our Tel Aviv facility or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce either MGuard Prime EPS or Cguard EPS stents.

Finally, the production of our stents must occur in a highly controlled, clean environment to minimize particles and other yield and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and results of operations.

Pre-clinical and clinical trials will be lengthy and expensive, and any delay or failure of clinical trials could prevent us from commercializing our MicroNet products, which would materially and adversely affect our results of operations and the value of our business.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including, if we seek in the future to sell our products in the

United States, the U.S. Food and Drug Administration. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. They require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. In some trials, a greater number of patients and a longer follow-up period may be required. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our existing products and those under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials. In addition, market demand may change for products being tested due to the length of time needed to complete requisite clinical trials. For example, we decided to discontinue our MASTER II trial notwithstanding the resources we had spent on the trial due to the change in market demand for bare metal stents.

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our stents provides a safe and effective alternative to other existing treatments for coronary artery disease and carotid artery disease.

We believe that physicians will not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our products provide a safe and effective alternative to other existing treatments for the conditions we are seeking to address.

If we fail to demonstrate safety and efficacy that is at least comparable to existing and future therapies available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Clinical trials conducted with our products may involve procedures performed by physicians who are technically proficient and are high-volume stent users of such products. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our products will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

Physicians currently consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. None of our current coronary products is a drug-eluting stent, and this may adversely affect our business.

Our ability to attract customers depends to a large extent on our ability to provide goods that meet the customers' and the market's demands and expectations. If we do not have a product that is expected by the market, we may lose customers. The market demand has shifted away from bare metal stents in favor of drug-eluting stents. Our MGuard Prime EPS is a bare-metal stent product, and we have noticed a reduction in the sales level of MGuard Prime EPS compared to the sales level we had in the past. Such sales may never recover and we do not currently have the resources to develop a drug-eluting stent product. Our failure to provide industry standard devices could adversely affect our business, financial condition and results of operations.

Our products are based on a new technology, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory approvals, if such approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Because our products are new and long-term success measures have not been completely validated, regulatory agencies may take a significant amount of time in evaluating product approval applications. Treatments may exhibit a favorable measure using one metric and an unfavorable measure using another metric. Any change in accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only six employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the pr