InspireMD, Inc.
Form S-1/A
March 22, 2013

As filed with the Securities and Exchange Commission on March 22, 2013

File No. 333-184066

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

AMENDMENT NO. 5 TO
FORM S-1
REGISTRATION STATEMENT UNDER THE
SECURITIES ACT OF 1933

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**26-2123838**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

4 Menorat Hamaor St.
Tel Aviv, Israel 67448
972-3-691-7691

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Alan Milinazzo
President and Chief Executive Officer
InspireMD, Inc.
4 Menorat Hamaor St.
Tel Aviv, Israel 67448
972-3-691-7691

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To be Registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee
Common Stock, par value $0.0001 per share		
Series A Convertible Preferred Stock, par value $0.0001 per share		
Total	$ 34,500,000 [2]	$ 4,705.80 [3]

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes shares that the underwriters have the option to purchase to cover overallotments, if any.

(3) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion) **Dated March 22, 2013**

11,111,111 Shares of Common Stock
11,111 Shares of Series A Convertible Preferred Stock

We are offering 11,111,111 shares of our common stock and 11,111 shares of our Series A Convertible Preferred Stock (Preferred Stock). This prospectus also relates to the offering of the shares of common stock issuable upon conversion of the Preferred Stock. We intend to sell securities with an aggregate purchase price of $30 million in this offering, with each purchaser having the option to choose whether to purchase common stock, Preferred Stock, or a combination of common stock and Preferred Stock. For each share of Preferred Stock purchased in the offering, we will reduce the number of shares of common stock being sold in the offering by 1,000. Our common stock is quoted on the OTC Bulletin Board under the symbol NSPR. On March 18, 2013, the last reported sale price of our common stock was $2.70 per share.

We have applied to list our shares of common stock on the NYSE MKT under the symbol NSPR. We are not listing our Preferred Stock on an exchange or any trading system and we do not expect that a trading market for our Preferred Stock will develop.

Each share of Preferred Stock is convertible into 1,000 shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will receive a payment equal to $0.0001 per share of Preferred Stock before any proceeds are distributed to the holders of our common stock. Each holder of Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder is then convertible with respect to any and all matters presented to the stockholders for their action or consideration. Holders of Preferred Stock vote together with the holders of common stock as a single class, except as provided by law and except that the consent of holders of a majority of the outstanding Preferred Stock will be required to amend the terms of the Preferred Stock.

Our business and an investment in our common stock or Preferred Stock involve significant risks. These risks are described under the caption Risk Factors beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price of common stock	$	$
Underwriting discount for common stock(1)	$	$
Public offering price of Preferred Stock	$	$
Underwriting discount for Preferred Stock(1)	$	$
Proceeds, before expenses, to InspireMD, Inc.	$	$

(1) The underwriters will receive compensation in addition to the discount. See Underwriting for a description of compensation payable to the underwriters.

The underwriters may also purchase up to an additional 1,666,666 shares of common stock from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallotments.

The underwriters expect to deliver the shares against payment in New York, New York on , 2013.

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JMP Securities

, 2013

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Information contained on our website is not part of this prospectus.

Unless otherwise indicated, all information in this prospectus reflects a one-for-four reverse stock split of our common stock that occurred on December 21, 2012.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under Risk Factors beginning on page 12 and our financial statements and notes thereto that appear elsewhere in this prospectus. As used in this prospectus, unless the context otherwise indicates, the terms we, our, us, or the Company for periods prior to the closing of our share exchange transaction on March 31, 2011 refer to InspireMD Ltd., a private company incorporated under the laws of the State of Israel that is now our wholly-owned subsidiary, and its subsidiary, taken as a whole, and the terms we, our, us, or the Company for periods subsequent to the closing of the share exchange transactions refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries, including InspireMD Ltd., taken as a whole.

Unless otherwise indicated, all information in this prospectus reflects a one-for-four reverse stock split of our common stock that occurred on December 21, 2012.

The Company

Overview

We are a medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. Since our formation, we have experienced net losses. We had a net loss of approximately $9.4 million during the six months ended December 31, 2012, a net loss of approximately $7.1 million during the six month transition period ended June 30, 2012, and a net loss of approximately $14.7 million during the fiscal year ended December 31, 2011. 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. Further, the report of Kesselman & Kesselman C.P.A.s (Isr.), our independent registered public accounting firm, with respect to our financial statements at June 30, 2012, December 31, 2011 and 2010, for the six month period ended June 30, 2012, and years ended December 31, 2011, 2010 and 2009 contains an explanatory paragraph as to our potential inability to continue as a going concern.

Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). According to the TYPHOON STEMI trial (New England Journal of Medicine, 2006) and the SOS SVG Trial (Journal of the American College of Cardiology, 2009), of patients with acute myocardial infarction and saphenous vein graft coronary interventions, 7.5% to 44% experience major adverse cardiac events, including cardiac death, heart attack and restenting of the artery. When performing stenting procedures in patients with acute coronary symptoms, interventional cardiologists face a difficult dilemma in choosing between bare-metal stents, which have a high rate of restenosis (formation of new blockages), and drug-eluting (drug-coated) stents, which have a high rate of late thrombosis (formation of clots months or years after implantation), require administration of anti-platelet drugs for at least one year post procedure, are more costly than bare-metal stents and have additional side effects. We believe that MGuard is a simple and seamless solution for these patients.

We also intend to apply our technology to develop additional products used for other vascular procedures, specifically carotid (the arteries that supply blood to the brain) and peripheral (other arteries) procedures.

In October 2007, our first generation product, the MGuard Coronary, received CE Mark approval for treatment of coronary arterial disease in the European Union. CE Mark is a mandatory conformance mark on many products marketed in the European Economic Area and certifies that a product has met European Union consumer safety, health or environmental requirements. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Southeast Asia, India, Latin America and Israel. During the summer of 2012, we submitted an investigational device exemption application to the U.S. Food and Drug Administration to conduct a pivotal trial that we intend to form the basis of an application to sell and market MGuard Coronary in the United States. On August 29, 2012, this

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application was denied due to numerous deficiencies. On December 17, 2012, we submitted a revised application to the U.S. Food and Drug Administration that addressed the issues cited in the disapproval letter. In addition, we substantially changed the design of the planned trial at that time. On January 18, 2013, the U.S. Food and Drug Administration issued us a second letter disapproving our investigational device exemption application. The U.S. Food and Drug Administration noted that although our December 17, 2012 letter addressed some of the issues cited in the August 29, 2012 disapproval letter, there remained additional deficiencies to be addressed to support the initiation of a human clinical study. We are currently in discussions with the U.S. Food and Drug Administration as to the resolution of these deficiencies. The enrollment initiation for the study is expected to occur in the second calendar quarter of 2013. Moreover, the enrollment phase for the study is expected to last 15 months and we expect that subjects in the study will be followed for 13 months with assessments at 30 days, six months and 12 months, with angiographic subgroup analysis occurring after the thirteenth month. These figures and dates, however, may change based on the final design of the study that is approved by the U.S. Food and Drug Administration. Presently, none of our products may be sold or marketed in the United States. See Business Future Clinical Trial for MGuard Coronary U.S. Food and Drug Administration Trial.

Our initial MGuard Coronary products incorporated a stainless steel stent. We subsequently replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as the MGuard Prime™ version of our MGuard Coronary. We believe the new platform will prove to be superior because cobalt-chromium stents are generally known in the industry to provide better deliverability and possibly even a reduction in major adverse cardiac events.

The MGuard Prime version of the MGuard Coronary received CE Mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. We believe we can use and leverage the clinical trial results of our original stainless steel based MGuard Coronary to market our new cobalt-chromium based MGuard Prime version of the MGuard Coronary.

Unless otherwise indicated, in this prospectus, references to MGuard Coronary are to both our initial stainless steel based MGuard Coronary and our more current cobalt-chromium based MGuard Prime version of the MGuard Coronary, as applicable.

For the six months ended December 31, 2012, our total revenue was approximately $1.9 million and our net loss was approximately $9.4 million. For the six months ended June 30, 2012, our total revenue was approximately $2.1 million and our net loss was approximately $7.1 million. For the year ended December 31, 2011, our total revenue was approximately $6.0 million and our net loss was approximately $14.7 million.

Recent Events

On June 1, 2012, our board of directors approved a change in our fiscal year-end from December 31 to June 30, effective June 30, 2012. This prospectus includes our financial results and other information for the six month period from January 1, 2012 through June 30, 2012, which we refer to as the transition period. Following the transition period, we will file annual reports for each twelve month period ended June 30 of each year beginning with the twelve month period ended June 30, 2013.

On October 24, 2012, we published the results of our MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial), a prospective, randomized study in Europe, South America and Israel to compare the MGuard Coronary 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 most severe form of heart

attack. The MASTER Trial enrolled 433 subjects, 50% of whom were treated with an MGuard Coronary stent and 50% of whom were treated with a commercially-approved bare metal or drug-eluting stent. The MASTER Trial demonstrated that among patients with acute STEMI undergoing emergency percutaneous coronary intervention, or angioplasty, MGuard Coronary 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. However, each of MGuard Coronary and commercially-approved bare metal or drug-eluting stents showed similar rates of major adverse cardiac events 30 days following the procedure.

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We effectuated a one-for-four reverse stock split on December 21, 2012 in order to bring our stock price into compliance with the listing requirements of the NYSE MKT, on which we have applied for listing.

On January 3, 2013, Ofir Paz resigned as our chief executive officer, and Alan Milinazzo was appointed as our new president, chief executive officer and member of the board of directors. Mr. Paz remains as a member of our board of directors.

Our Industry

According to Fact Sheet No. 310/updated June 2011 of the World Health Organization, approximately 7.3 million people worldwide died of coronary heart disease in 2008. 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. A stent is an expandable scaffold-like device, usually constructed of a stainless steel material, that is inserted into an artery to expand the inside passage and improve blood flow.

According to the 2012 MEDTECH OUTLOOK produced in January 2012 by the Bank of Montreal Investment Banking Group, known as BMO Capital Markets, 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. The growth in volume is due to the appeal for less invasive percutaneous coronary intervention procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Coronary artery disease is one of the leading causes of death worldwide. The treatment of coronary artery disease includes alternative treatment methodologies, that is, coronary artery bypass grafting or angioplasty (percutaneous coronary intervention) with or without stenting. According to the 2012 MEDTECH OUTLOOK produced by the BMO Capital Markets in January 2012, the percutaneous coronary intervention procedures involving stents are increasingly being used to treat coronary artery diseases with a 71% penetration rate in 2010.

Our Products and Applications

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

MGuard 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.

MGuard Coronary with a bio-stable mesh. Our first MGuard product, the MGuard Coronary with a bio-stable mesh, is comprised of our mesh sleeve wrapped around a stainless steel bare-metal stent. The current MGuard Prime version of our MGuard Coronary with a bio-stable mesh is comprised of our mesh sleeve wrapped around a cobalt-chromium bare-metal stent. In comparison to a conventional bare-metal stent, we believe the MGuard Coronary with a bio-stable mesh provides protection from embolic showers. Results of clinical trials on the MGuard Coronary stent, including the MAGICAL, PISCIONE MGuard international registry (iMOS) clinical trials described below (see Business Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population below), as well as the MASTER trial, indicate positive outcomes and safety measures. The results of these clinical trials for the MGuard Coronary stent suggest higher levels of reperfusion

(blood flow through the microcirculatory system, those blood vessels which are the only visible with a microscope) and high levels of complete ST resolution (an indication that heart muscle activity has returned to normal), as compared to the levels and rates of other bare-metal and drug-eluting stents.

MGuard Coronary with a drug eluting bio-absorbable mesh. Based upon the clinical profile of MGuard Coronary, we anticipate that the MGuard Coronary with a drug-eluting bio-absorbable mesh will offer both the comparable levels of reperfusion and complete ST resolution as the MGuard Coronary with a bio-stable mesh, as described above, and a comparative restenosis rate, which is the rate at which patients experience formation of new blockages in their arteries, when compared to existing drug-eluting stents. This

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product is currently planned, but not yet under development. The bio-absorbability of MGuard Coronary with a drug eluting bio-absorbable mesh is intended to improve upon the bio-absorbability of other drug-eluting stents, in light of the large surface area of the mesh and the small diameter of the fiber. We intend to study whether the protective sleeve on the MGuard Coronary with a drug-eluting bio-absorbable mesh can improve uniform distribution of the applied drug to the vessel wall for improved drug therapy management compared to other drug-eluting stents, where the drug is distributed on the struts only. If this intended result is achieved with respect to the improved and uniform distribution of the applied drug to the vessel wall, the total dosage of the medication potentially could be reduced while increasing its efficacy. MGuard Coronary with a drug-eluting bio-absorbable mesh is expected to promote smooth and stable endothelial cell growth and subsequent attachment to the lumen of the vessel wall, which is essential for rapid healing and recovery. In addition, we believe bio-absorbable drug-eluting mesh may enable the use of more effective drug therapies that presently cannot be effectively coated on a metal-based stent due to their poor diffusion capabilities. Because the drug-eluting bio-absorbable mesh will be bio-absorbable, we anticipate that the mesh will completely dissolve after four months, which we expect will result in fewer of the chronic long term side effects that are associated with the presence of the drug.

MGuard Carotid Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in carotid-applications. This product is currently under development, although we have temporarily delayed its development until additional funding is secured. We believe that our MGuard design will provide substantial advantages over existing therapies in treating carotid artery stenosis (blockage or narrowing of the carotid arteries), like conventional carotid stenting and endarterectomy (surgery to remove blockage), given the superior embolic protection characteristics witnessed in coronary arterial disease applications. We intend that the embolic protection will result from the mesh sleeve, as it traps emboli at their source. In addition, we believe that MGuard Carotid will provide post-procedure protection against embolic dislodgement, which can occur immediately after a carotid stenting procedure and is often a source of post-procedural strokes in the brain. Schofer, et al. (Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging, *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have also shown that the majority of the incidents of embolic showers associated with carotid stenting occur immediately post-procedure.

MGuard Peripheral Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in peripheral applications. This product is currently under development, although we have temporarily delayed its development until additional funding is secured. Peripheral Artery Disease, also known as peripheral vascular disease, is usually characterized by the accumulation of plaque in arteries in the legs, need for amputation of affected joints 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 covered stents, at the risk of blocking branching vessels, to ensure that emboli does not fall into the bloodstream. We believe that our MGuard design will provide substantial advantages over existing therapies in treating peripheral artery stenosis (blockage or narrowing of the peripheral arteries).

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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.,* CQ1-2013 means January 1, 2013 through March 31, 2013). While we currently anticipate seeking approval from the U.S. Food and Drug Administration for all of our products in the future, we have only outlined an estimated timetable to seek U.S. Food and Drug Administration approval for our MGuard Coronary with bio-stable mesh product in our current business plan. 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	Start Development	CE Mark	European Union Sales	FDA Approval	U.S. Sales
MGuard Coronary Plus Bio-Stable Mesh	Bypass/ Coronary	2005	Oct. 2007	CQ1-2008	CQ2-2016	2016
MGuard Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	CQ1-2011	To be determined	To be determined	To be determined	To be determined
MGuard Carotid Plus Bio-Stable Mesh	Carotid Arteries	CQ1-2011	To be determined (submitted for approval January 2013)	To be determined	To be determined	To be determined
MGuard Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	To be determined	To be determined	To be determined	To be determined	To be determined

With respect to MGuard Carotid with bio-stable mesh and MGuard Peripheral with bio-stable mesh, we have determined that the expected commencement of sales in the European Union cannot be accurately predicted since we have delayed the development of these products until additional funding for their development is secured.

We anticipate that our MGuard Coronary with bio-stable mesh will be classified as a Class III medical device 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 MGuard Coronary with bio-stable mesh. We have begun commercialization of MGuard Coronary with a bio-stable mesh in Europe, Russia, Asia and Latin America through our distributor network and we are aggressively pursuing additional registrations and contracts in other countries such as Canada, South Korea and certain smaller countries in Latin America. By the time we begin marketing this product in the United States, we expect to have introduced the MGuard Coronary technology to clinics and interventional cardiologists

around the world, and to have fostered brand name recognition and widespread adoption of MGuard Coronary. We plan to accomplish this by participating in national and international conferences, conducting and sponsoring clinical trials, publishing articles in scientific journals, holding local training sessions and conducting electronic media campaigns.

Successfully develop the next generation of MGuard stents. While we market our MGuard Coronary with bio-stable mesh, we intend to develop the MGuard Coronary with a drug-eluting mesh. We are also working on our MGuard stents for carotid, for which we submitted an application

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for CE Mark approval in January 2013. In addition, we released our cobalt-chromium version of MGuard Coronary, MGuard Prime, in 2010, which we anticipate will replace the original stainless steel-based version of MGuard Coronary over the next few years.

Continue to leverage MGuard 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 are securing intellectual property rights using our mesh technology in the areas of brain aneurism, treating bifurcated blood vessels and a new concept of distal protective devices. We believe these areas have large growth potential given, in our view, that present solutions are far from satisfactory, and there is a significant demand for better patient care. We believe that our patents, and patent applications once allowed, can be put into practice and that they will drive our growth at a later stage.

Work with world-renowned physicians to build awareness and brand recognition of MGuard portfolio of products. We intend to work closely with leading cardiologists to evaluate and ensure the efficacy and safety of our products. We intend that some of these prominent physicians will serve on our Scientific Advisory Board, which is our advisory committee that advises our board of directors, and run clinical trials with the MGuard Coronary stent. We believe these individuals, once convinced of the MGuard Coronary stent s appeal, will be invaluable assets in facilitating the widespread adoption of the stent. In addition, we plan to look to these cardiologists to generate and publish scientific data on the use of our products, and to present their findings at various conferences they attend.

Continue to protect and expand our portfolio of patents. Our patents and their protection are critical to our success. We have filed nine separate patent applications for our MGuard technology in the United States (including one that is still in the Patent Cooperation Treaty international phase) 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 continue patenting new technology as it is developed, and to actively pursue any infringement covered by any of our patents. To date, we have secured patent protection in China for four patents and in each of the United States and South Africa for one patent. See Business Intellectual Property Patents.

Risks Associated with Our Business

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as discussed more fully in the section titled Risk Factors, including, without limitation:

our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;

our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;

our ability to adequately protect our intellectual property;

the risk that one or more third parties might allege violation of their intellectual property rights in a way that hinders or prevents commercialization of our products;

our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that the MGuard technology is an attractive alternative to other procedures and products;

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intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;

entry of new competitors and products and potential technological obsolescence of our products;

loss of a key customer or supplier;

technical problems with our research and products and potential product liability claims;

adverse economic conditions;

adverse federal, state and local government regulation, in the United States, Europe or Israel;

price increases for supplies and components;

inability to carry out research, development and commercialization plans; and

loss or retirement of key executives and research scientists.

Corporate and Other Information

We were organized in the State of Delaware on February 29, 2008 as Saguaro Resources, Inc. to engage in the acquisition, exploration and development of natural resource properties. On March 28, 2011, we changed our name from Saguaro Resources, Inc. to InspireMD, Inc.

Our principal executive offices are located at 4 Menorat Hamaor St., Tel Aviv, Israel 67448. Our telephone number is 972-3-691-7691. 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.

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The Offering[1]

Common Stock	
Common stock offered by the Company:	11,111,111 shares (or 12,777,777 shares if the underwriters exercise in full their overallotment option to purchase additional shares)[2]
Common stock to be outstanding after this offering:	29,709,340 shares (or 31,376,006 shares if the underwriters exercise in full their overallotment option to purchase additional shares)[2]
OTC Bulletin Board symbol:	NSPR
Proposed symbol and listing:	We have applied to list our shares of common stock on the NYSE MKT under the symbol NSPR.
Series A Convertible Preferred Stock	
Preferred Stock offered by the Company:	11,111 shares[3]
Conversion:	Each share of our Preferred Stock is convertible into 1,000 shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding.
Liquidation Preference:	In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will receive a payment equal to $0.0001 per share of Preferred Stock before any proceeds are distributed to the holders of our common stock.
Voting rights:	Each holder of Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder is then convertible with respect to any and all matters presented to the stockholders for their action or consideration. Holders of Preferred Stock vote together with the holders of common stock as a single class, except as provided by law and except that the consent of holders of a majority of the outstanding Preferred Stock will be required to amend the terms of the Preferred Stock.
Dividends:	Shares of Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors.
Listing:	We are not listing our Preferred Stock on an exchange or any trading system and we do not

expect that a trading market for our Preferred Stock will develop.

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Use of proceeds:	We intend to use the net proceeds of this offering to redeem our convertible debentures, to support the worldwide commercialization of MGuard in acute myocardial infarction and pursue U.S. Food and Drug Administration approval in the United States, and for general corporate purposes. See Use of Proceeds beginning on page 32 of this prospectus.
Risk factors:	You should carefully consider the information set forth in this prospectus and, in particular, the specific factors set forth in the Risk Factors section beginning on page 12 of this prospectus before deciding whether or not to invest in our securities.

(1) All share amounts are adjusted for the one-for-four reverse stock split that occurred on December 21, 2012.

(2) Based on an assumed offering price of $2.70 per share (which is the last reported sales price of our common stock on March 18, 2013).

(3) Based on an assumed offering price of $2,700 per share (which is equal to the last reported sales price of our common stock on March 18, 2013 multiplied by 1,000). For each share of Preferred Stock purchased in the offering, we will reduce the number of shares of common stock being sold in the offering by 1,000.

The number of shares of common stock outstanding after this offering is based on 18,598,229 shares outstanding on March 18, 2013 and excludes:

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;

57,974 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $4.93 per share;

1,798,876 shares of common stock issuable upon the conversion of our senior secured convertible debentures due April 5, 2015;

3,612,737 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.001 to $10.40 and having a weighted average exercise price of $4.72 per share;

1,618,650 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan; and

any additional shares of common stock that we would be required to issue to the investors in our March 31, 2011 financing in the event that the actual offering price of our common stock in this offering is below $6.00 per share and/or the actual offering price of our Preferred Stock in this offering is below $6,000 per share. Based on an assumed offering price of $2.70 per share of common stock (which is the last reported sales price of our common stock on March 18, 2013) and $2,700 per share of Preferred Stock, we would be required to issue 460,943 additional shares of common stock to our March 31, 2011 investors. See Risk Factors Risks Related to Our Organization, Our Securities and This Offering Should we issue shares of common stock in this offering below $6.00 per share and/or shares of Preferred Stock in this offering below $6,000 per share, it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing.

Unless otherwise stated, all information contained in this prospectus assumes no exercise of the overallotment option granted to the underwriters.

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Summary Consolidated Financial Data

The following summary consolidated financial data should be read in conjunction with the consolidated financial statements and the related notes thereto and the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus. The balance sheet data at June 30, 2012 and the statement of operations data for the six months ended June 30, 2012 and each of the years ended December 31, 2011, 2010 and 2009 have been derived from the audited consolidated financial statements for such years, included in this prospectus. The balance sheet data at December 31, 2012 and the statement of operations data for the six months ended December 31, 2012 and 2011 have been derived from the unaudited consolidated financial statements for such periods, included in this prospectus. Our historical results are not necessarily indicative of the results to be expected for the full fiscal year.

The historical share and per share amounts set forth below reflect the one-for-four reverse stock split of our common stock that occurred on December 21, 2012.

Statement of Operations Data

	Six Months Ended June 30, 2012	Year Ended December 31, 2011	2010	2009	Six Months Ended December 31, 2012 (unaudited)	2011 (unaudited)
	(amounts in thousands, except per share and percentage data)					
Revenues	$2,071	$6,004	$4,949	$3,411	$1,859	$3,278
Cost of revenues	$1,377	$3,011	$2,696	$2,291	$777	$1,472
Gross profit (loss)	$694	$2,993	$2,253	$1,120	$1,082	$1,806
Gross margin	34 %	50 %	46 %	33 %	58 %	55 %
Total operating expenses	$7,852	$16,722	$5,472	$3,837	$8,729	$12,193
Net loss	$(7,081)	$(14,665)	$(3,420)	$(2,724)	$(9,426)	$(10,516)
Net loss per share basic and diluted	$(0.42)	$(0.95)	$(0.28)	$(0.23)	$(0.54)	$(0.64)
Weighted average number of ordinary shares used in computing net loss per share basic and diluted	17,044,220	15,359,925	12,308,632	11,914,713	17,401,025	16,374,636
As adjusted[(1)] net loss per share basic and diluted (Unaudited)	$(0.76)	$(0.95)	$(0.28)	$(0.23)	$(0.33)	$(0.64)
As adjusted[(1)] weighted average number of ordinary shares used computing net loss per share basic and diluted (Unaudited)	19,311,299	15,359,925	12,308,632	11,914,713	22,255,241	16,374,636

(1) The unaudited as adjusted amounts give effect to our receipt of the net proceeds from the sale by us in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the application of the net proceeds we will receive from this offering, to redeem the convertible debentures, as described in Use of Proceeds. The unaudited as adjusted amounts assume that all purchasers elect to purchase common stock. The As adjusted weighted average number of ordinary shares used computing net loss per share basic and diluted only includes the number of shares issued in order to redeem the loan and not the total shares issued in the offering.

The increase in the As adjusted net loss per share basic and diluted for the six months ended June 30, 2012 was due to high financial expenses resulting from the amortization of the convertible debentures to the redemption value. The decrease in the As adjusted net loss per share basic and diluted for the six months ended December 31, 2012 was due to the cancelation of the financial expenses related to the convertible debentures following its redemption.

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Balance Sheet Data

	December 31, 2012 (unaudited)	
	Actual	As adjusted[1]
Cash and cash equivalents	$ 5,433	$ 19,977
Restricted cash	$ 93	$ 93
Working capital[2]	$ (430)	$ 20,575
Total assets	$ 11,597	$ 25,365
Long-term liabilities	$ 1,861	$ 1,861
Equity	$ 204	$ 20,433

(1) The unaudited as adjusted amounts give effect to our receipt of the net proceeds from the sale by us in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the application of the net proceeds we will receive from this offering to redeem the convertible debentures, as described in Use of Proceeds.

(2) Working capital is equal to the difference between total current assets and total current liabilities.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below and all of the other information set forth in this prospectus before deciding to invest in our securities. If any of the events or developments described below occur, our business, financial condition or results of operations could be negatively affected. In that case, the trading price of our securities could decline, and you could lose all or part of your investment in our securities.

Risks Related to Our Business

The report of our independent auditors contains 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 and have significant future commitments, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Further, the report of Kesselman & Kesselman C.P.A.s (Isr.), our independent registered public accounting firm, with respect to our financial statements at June 30, 2012, December 31, 2011 and 2010, and for the six month transition period ended June 30, 2012, and the years ended December 31, 2011, 2010 and 2009 contains an explanatory paragraph as to our potential inability to continue as a going concern. Additionally, the doubts regarding our potential inability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

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. Furthermore, we have significant future commitments with respect to our convertible debentures. Since we expect to continue incurring negative cash flows from operations and in light of the potential cash expenditures that may be required to satisfy our convertible debentures, there can be no assurance that we will ever generate sufficient revenues to become profitable.

We expect to derive our revenue from sales of our MGuard stent products and other products we may develop. If we fail to generate revenue from this source, 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 stent products and other products we may develop. Future sales of these products, if any, will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. If we fail to generate such revenues, 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.

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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 United States 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. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the United States, and many companies have encountered significant difficulties in protecting, enforcing, and defending such rights in certain foreign jurisdictions. 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 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.

We have limited manufacturing capabilities and manufacturing personnel, and 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 stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard stent 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 stent 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.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our MGuard stent in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or scale up, the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities will require the investment of substantial

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are una

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funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If unable to do so, we may not be able to meet potential future demand. If we are unable to manufacture a sufficient supply of our MGuard stent, our revenues, business and financial prospects would be adversely affected and we may suffer reputational harm, which could further adversely affect our revenues, business and financial prospects. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

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

Finally, the production of our MGuard stent 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.

The U.S. Food and Drug Administration may not approve our investigational device exemption application for a pivotal trial of our MGuard Coronary with bio-stable mesh, which would prevent us from conducting our clinical trials in the United States, and even if the U.S. Food and Drug Administration does grant such approval, our clinical trials may be more costly and burdensome than we currently anticipate, which would limit or delay our ability to complete clinical trials and ultimately market our MGuard Coronary with bio-stable mesh in the United States.

In connection with our efforts to seek approval of our MGuard Coronary with bio-stable mesh by the U.S. Food and Drug Administration, we filed an investigational device exemption application with the U.S. Food and Drug Administration during the summer of 2012 to conduct a pivotal trial. On August 29, 2012, the U.S. Food and Drug Administration issued us a letter disapproving our investigational device exemption application due to insufficient data to support the initiation of a human clinical study. More specifically, the U.S. Food and Drug Administration cited numerous deficiencies in our application which may require, amongst other things, new and/or repeated testing in order to resolve. On December 17, 2012, we sent a letter in response to the U.S. Food and Drug Administration that addressed the issues cited in the disapproval letter. In addition, we substantially changed the design of the planned trial at that time. On January 18, 2013, the U.S. Food and Drug Administration issued us a second letter disapproving our investigational device exemption application. The U.S. Food and Drug Administration noted that although our December 17, 2012 letter addressed some of the issues cited in the August 29, 2012 disapproval letter, there remained additional deficiencies to be addressed to support the initiation of a human clinical study. We are currently re-evaluating the entirety of our investigational device exemption application that we sent to the U.S. Food and Drug Administration and are in discussions with the U.S. Food and Drug Administration regarding our investigational device exemption application and planned human clinical study, including clinical protocol. We may determine that it is necessary to modify some or all components of our investigational device exemption application and planned human clinical study. Subject to the outcome of our discussions with the U.S. Food and Drug Administration, the enrollment initiation for the study is expected to occur in the second calendar quarter of 2013. Moreover, the

enrollment phase for the study is expected to last 15 months and we expect that subjects in the study will be followed for 13 months with assessments at 30 days, six months and 12 months, with angiographic subgroup analysis occurring after the thirteenth month. These figures and dates, however, may change based on the final design of the study that is approved by the U.S. Food and Drug Administration. There can be no assurance that we will be able to resolve these deficiencies and secure approval of our investigational device exemption application from the U.S. Food and Drug Administration.

If the U.S. Food and Drug Administration does not approve our investigational device exemption application, we would be unable to conduct a pivotal trial of our MGuard Coronary with bio-stable mesh, thereby preventing us from marketing MGuard Coronary with bio-stable mesh in the United States. Not being able to market MGuard Coronary with bio-stable mesh in the United States would have an adverse effect on

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our business. Moreover, even if the U.S. Food and Drug Administration approves an investigational device exemption application to conduct a pivotal trial, the clinical study we conduct may have unanticipated complications and delays, may be more costly than we currently anticipate, and/or may fail to achieve the primary or secondary endpoints. The U.S. Food and Drug Administration may approve our investigational device exemption application with conditions relating to the scope or design of our clinical trials for which we have not planned. These conditions may require us to collect additional data, enroll more patients, spend more time and expend more resources than we currently anticipate, and these conditions may make a clinical trial in the United States more costly and time consuming than we currently plan. Any unanticipated costs and length of U.S. clinical trials, along with our failure to achieve primary or secondary endpoints would delay, if not prevent, our ability to market our MGuard Coronary with bio-stable mesh in the United States, which would harm our business.

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard stent will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard stent will be expensive and will 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. Clinical trials supporting a pre-market approval applications for the Cypher stent developed by Johnson & Johnson and the Taxus Express2 stent developed by Boston Scientific Corporation, which were approved by the U.S. Food and Drug Administration and are currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. In some trials, a greater number of patients and a longer follow up period may be required. The U.S. Food and Drug Administration may require us to submit data on a greater number of patients or for a longer follow-up period than those for pre-market approval applications for the Cypher stent and the Taxus Express2 stent. 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 products 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.

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

We believe that physicians will not widely adopt the MGuard stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our MGuard stent provides a safe and effective alternative to other existing treatments for coronary artery disease, including coronary artery bypass grafting balloon angioplasty, bare-metal stents and other drug-eluting stents, provided by Johnson & Johnson, Boston Scientific Corporation, Medtronic Inc., Abbott Laboratories and others.

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We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the MGuard stents are an attractive alternative to other procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug-eluting stents or bare-metal stents that have received regulatory approval and that are available on the market, our ability to successfully market the MGuard stent 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 MGuard stent will vary. Clinical trials conducted with the MGuard Coronary stent have involved procedures performed by physicians who are technically proficient and are high-volume stent users. 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 MGuard Coronary stent 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.

In addition, currently, physicians consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. While we believe that the MGuard Coronary stent is a safe and effective alternative, it is not a drug-eluting stent, which may further hinder its support and adoption by physicians.

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, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the 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 eight employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. There can be no assurance that such approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair,

replacement or refund of the cost of, any device manufactured or sold by us. Furthermore, there can be no assurance that all necessary regulatory approvals will be obtained for the manufacture, marketing and sale in any market of any new product developed or that any potential licensee will develop using our licensed technology.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval in the United States, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual

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review and periodic inspections by the U.S. Food and Drug Administration and other regulatory bodies. In particular, we and our suppliers will be required to comply with the U.S. Food and Drug Administration s Quality System Regulation for the manufacture of our MGuard stent, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval in the United States. The U.S. Food and Drug Administration enforces the Quality System Regulation through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the U.S. Food and Drug Administration and will have to successfully complete such inspections before we receive U.S. regulatory approval for our products. Failure by us or one of our suppliers to comply with statutes and regulations administered by the U.S. Food and Drug Administration and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

warning letters or untitled letters;
fines and civil penalties;
unanticipated expenditures;
delays in approving, or refusal to approve, our products;
withdrawal or suspension of approval by the U.S. Food and Drug Administration or other regulatory bodies;
product recall or seizure;
orders for physician notification or device repair, replacement or refund;
interruption of production;
operating restrictions;
injunctions; and
criminal prosecution.

If any of these actions were to occur, it could harm our reputation and could cause our product sales and profitability to suffer. Furthermore, key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval of a product is granted in the United States, the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the U.S. Food and Drug Administration determines that our promotional materials, training or other activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Moreover, any modification to a device that has received U.S. Food and Drug Administration approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the U.S. Food and Drug Administration. If the U.S. Food and Drug Administration disagrees with any determination by us that new approval is not required, we may be required to cease marketing or to recall the modified product until approval is obtained. In addition, we could also be subject to significant regulatory fines or penalties.

Additionally, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, such as Quality System Regulation, may result in restrictions on such

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regula

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regula

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products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. In addition, the healthcare regulatory environment may change in a way that restricts our operations.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products in such jurisdictions.

We intend to market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from those obtained in the United States and Europe. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE Mark or U.S. Food and Drug Administration approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE Mark or U.S. Food and Drug Administration approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE Mark does not ensure approval by regulatory authorities in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in certain markets.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies in the United States and internationally in connection with our current product and products under development. We face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. When we commercialize our products, we expect to face intense competition from Cordis Corporation, a subsidiary of Johnson & Johnson, Boston Scientific Corporation, Guidant, Medtronic, Inc., Abbott Vascular Devices, Terumo and others. 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. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

We may become subject to claims by much larger and better capitalized competitors seeking to invalidate our intellectual property or our rights thereto.

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 MGuard stent based on one or more of these patents. It is also possible that a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us of which we are not aware. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. As the number of competitors in the stent market grows, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their

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competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

If we fail to maintain or establish satisfactory agreements with suppliers, we may not be able to obtain materials that are necessary to develop our products.

We depend on outside suppliers for certain raw materials. These raw materials or components may not always be available at our standards or on acceptable terms, if at all, and we may be unable to locate alternative suppliers or produce necessary materials or components on our own.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. We depend on QualiMed Innovative Medizinprodukte GmbH, which manufactures the body of the stent, MeKo Laserstrahl-Materialbearbeitung for the laser cutting of the stent, Natec Medical Ltd. for the supply of catheters and Biogeneral Inc. for the fiber. We may have difficulty obtaining similar components from other suppliers that are acceptable to the U.S. Food and Drug Administration or foreign regulatory authorities if it becomes necessary.

If we have to switch to a replacement supplier, we will face additional regulatory delays and the interruption of the manufacture and delivery of our MGuard stent for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the U.S. Food and Drug Administration or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

We may be exposed to product liability claims and insurance may not be sufficient to cover these claims.

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in clinical trials. We may also be exposed to product liability claims based on the sale of any such products following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our business. We also have liability insurance for an ongoing clinical trial in Europe. Insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverages, or expand our insurance coverage to include future clinical trials or the sale of products incorporating our licensed technology if marketing approval is obtained for such products, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

We may implement a product recall or voluntary market withdrawal due to product defects or product enhancements and modifications, which would significantly increase our costs.

The manufacturing and marketing of our MGuard stent products involves an inherent risk that our products may prove to be defective. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall of one of our products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and safety.

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The successful management of operations depends on our ability to attract and retain talented personnel.

We depend on the expertise of our senior management and research personnel, which would be difficult to replace. The loss of the services of any of our senior management could compromise our ability to achieve our objectives. Furthermore, recruiting and retaining qualified personnel will be crucial to future success. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the competition among medical device, biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced management, scientists, researchers, sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel, our operations may be jeopardized and our results of operations may be materially and adversely affected.

We are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations.

We operate globally and develop and manufacture products in our research and manufacturing facilities in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International sales and operations are subject to a variety of risks, including:

foreign currency exchange rate fluctuations;
greater difficulty in staffing and managing foreign operations;
greater risk of uncollectible accounts;
longer collection cycles;
logistical and communications challenges;
potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
changes in labor conditions;
burdens and costs of compliance with a variety of foreign laws;
political and economic instability;
increases in duties and taxation;
foreign tax laws and potential increased costs associated with overlapping tax structures;
greater difficulty in protecting intellectual property;
the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and
general economic and political conditions in these foreign markets.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

If we fail to obtain an adequate level of reimbursement for our products by third party payors, there may be no commercially viable markets for our product candidates or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payors affect the market for our product candidates. The efficacy, safety, performance and cost-effectiveness of our product

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candidates and of any competing products will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. There is increasing pressure by governments worldwide to contain health care costs by limiting both the coverage and the level of reimbursement for therapeutic products and by refusing, in some cases, to provide any coverage for products that have not been approved by the relevant regulatory agency. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and future revenues, if any, would be adversely affected.

In the United States and in the European Union, our business could be significantly and adversely affected by recent healthcare reform legislation and other administration and legislative proposals.

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in the United States were enacted into law in March 2010. Certain provisions of these acts will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation. The legislation levies a 2.3% excise tax, that began on January 1, 2013, on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. If we commence sales of our MGuard Coronary stent in the United States, this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

In the European Union, on September 26, 2012, the European Commission proposed a revision of the legislation currently governing medical devices. If adopted by the European Parliament and the Council in their present form,

these proposed revisions, which would be adopted in 2014 and would then gradually come into effect from 2015 to 2019, will impose stricter requirements on medical device manufacturers. Moreover, the supervising competences of the competent authorities of the European Union Member States and the notified bodies will be strengthened. The regulation of advanced therapy medicinal products is also in continued development in the European Union, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis. Any of these regulatory changes and events could limit our ability to form collaborations and our ability to continue to

In the United States and in the European Union, our business could be significantly and adversely affected by recen

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commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

Our strategic business plan may not produce the intended growth in revenue and operating income.

Our strategies include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected.

In addition, as part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the operations, technologies, services and products of the acquired companies and the diversion of management s attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We may have violated Israeli securities law.

We may have violated section 15 of the Israeli Securities Law of 1968. Section 15 of the Israeli Securities Law of 1968 requires the filing of a prospectus with the Israel Securities Authority and the delivery thereof to purchasers in connection with an offer or sale of securities to more than 35 parties during any 12-month period. We allegedly issued securities to more than 35 investors during certain 12-month periods, ending in October 2008. Our wholly-owned subsidiary, InspireMD Ltd., a private company incorporated under the laws of the State of Israel, applied for a no-action determination from the Israel Security Authority on February 14, 2011 in connection with the foregoing. To date, the Israel Securities Authority has not responded to InspireMD Ltd. s application for no-action determination and we are unable to predict when a response will be received. The maximum penalties for violating section 15 of the Israeli Securities Law of 1968 are as follows: imprisonment of five years; a fine of up to approximately $317,000 to be paid by management of the violating company; and a fine of up to approximately $1,590,000 to be paid by the violating company, any of which penalties could result in a material adverse effect on our operations. We believe that it is unlikely that either we or any individual will be subject to fines or other penalties as a result of these alleged violations.

Following the completion of this offering, 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 our stockholders ownership interests.

In order to fully realize all of our business objectives, we will need to raise additional capital following the completion of this offering, which may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

developing MGuard Carotid, MGuard Peripheral and MGuard Coronary with a drug eluting bio-absorbable mesh and any additional products;

pursuing growth opportunities, including more rapid expansion;
acquiring complementary businesses;
making capital improvements to improve our infrastructure;
hiring qualified management and key employees;
developing new services, programming or products;
responding to competitive pressures;
complying with regulatory requirements such as licensing and registration; and
maintaining compliance with applicable laws.

Following the completion of this offering, we will need to raise additionalcapital to meet our business requirements i

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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.

Risks Related to Operating in Israel

We anticipate being subject to fluctuations in currency exchange rates because we expect a substantial portion of our revenues will be generated in Euros and U.S. dollars, while a significant portion of our expenses will be incurred in New Israeli Shekels.

We expect a substantial portion of our revenues will be generated in U.S. dollars and Euros, while a significant portion of our expenses, principally salaries and related personnel expenses, is paid in New Israeli Shekels, or NIS. As a result, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the NIS in relation to the Euro or the U.S. dollar, or that the timing of this devaluation will lag behind inflation in Israel. Because inflation has the effect of increasing the dollar and Euro costs of our operations, it would therefore have an adverse effect on our dollar-measured results of operations. The value of the NIS, against the Euro, the U.S. dollar, and other currencies may fluctuate and is affected by, among other things, changes in Israel s political and economic conditions. Any significant revaluation of the NIS may materially and adversely affect our cash flows, revenues and financial condition. Fluctuations in the NIS exchange rate, or even the appearance of instability in such exchange rate, could adversely affect our ability to operate our business.

If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.

Our principal executive offices and our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying

in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. Recent political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the

If there are significant shifts in the political, economic and military conditionsin Israel and its neighbors, it could have

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region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service.

Many of our executive officers and key employees reside in Israel and may be required to perform annual military reserve duty. Currently, all male adult citizens and permanent residents of Israel under the age of 40 (or older, depending on their position with the Israeli Defense Forces reserves), unless exempt, are obligated to perform military reserve duty annually and are subject to being called to active duty at any time under emergency circumstances. Our operations could be disrupted by the absence for a significant period of one or more of our officers or key employees due to military service. Any such disruption could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to enforce covenants not-to-compete under current Israeli law.

We have non-competition agreements with many of our employees, most of which are governed by Israeli law. These agreements generally prohibit our employees from competing with us or working for our competitors for a specified period following termination of their employment. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for relatively brief periods of time in restricted geographical areas and only when the employee has unique value specific to that employer s business and not just regarding the professional development of the employee. Any such inability to enforce non-compete covenants may cause us to lose any competitive advantage resulting from advantages provided to us by such confidential information.

It may be difficult for investors in the United States to enforce any judgments obtained against us or any of our directors or officers.

All of our assets are located outside the United States and we do not currently maintain a permanent place of business within the United States. In addition, three of our directors and most of our officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

The tax benefits that are available to us require us to continue meeting various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

The tax benefits that are available to us require us to continue meeting various conditions and may be terminated or reduced in the future, which could increase our costs and taxes. InspireMD Ltd. has been granted a Beneficiary Enterprise status by the Investment Center in the Israeli Ministry of Industry Trade and Labor which made us eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. In order to remain eligible for the tax benefits of a Beneficiary Enterprise , we must continue to meet certain conditions stipulated in the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which may include, among other things, making specified investments in fixed assets and equipment, financing a percentage of those investments with our capital

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contributions, filing certain reports with the Investment Center, complying with provisions regarding intellectual property and the criteria set forth in the specific certificate of approval issued by the Investment Center or the Israel Tax Authority. If we do not meet these requirements, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. Further, in the future, these tax benefits may be reduced or discontinued. If these tax benefits are cancelled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2011 was 24% of their taxable income, was increased to 25% in 2012 and remains at such a rate in 2013. In the future, we may not be eligible to receive additional tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

Risks Related to Our Organization, Our Securities and This Offering

Should we issue shares of common stock in this offering at a price below $6.00 per share and/or shares of Preferred Stock in this offering below $6,000 per share it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing.

Pursuant to the terms of the securities purchase agreement that we entered into on March 31, 2011, in the event that we issue any shares of common stock on or before March 31, 2014 at a price per share less than $6.00 (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012), we are required, subject to certain limitations, to issue the investors in that financing additional shares of common stock, for no additional consideration, in an amount sufficient that the amount paid by each investor in the March 31, 2011 financing, when divided by the total number of shares issued to each such investor (in the original March 31, 2011 financing and as a result of this dilution adjustment) will result in an adjusted price per share price paid by these investors equal to the original price per share paid multiplied by a fraction, (A) the numerator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issuance plus (2) the number of shares of common stock that the aggregate consideration received by us in this offering would purchase at the original purchase price; and (B) the denominator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issuance plus (2) the number of such additional shares of common stock so issued, including those shares issuable upon conversion of the Preferred Stock. This formula is intended to be a weighted average dilution adjustment. As a result, in the event that we sell shares of common stock in this offering at a price below $6.00 per share and/or shares of Preferred Stock in this offering below $6,000 per share, it will result in the issuance of additional shares of common stock to our March 31, 2011 investors, which will be dilutive to all of our other stockholders, including new investors in this offering. Moreover, as the number of shares that we would be required to issue to our March 31, 2011 investors is based on a weighted average formula, the further the purchase price in this offering is below $6.00 for the common stock and $6,000 for the Preferred Stock, the greater the number of shares we will be required to issue to our March 31, 2011 investors. Based on an assumed offering price of $2.70 per share of common stock (which is the last reported sales price of the Company s common stock on March 18, 2013) and $2,700 per share of Preferred Stock, we would be required to issue 460,943 additional shares to these investors.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our securities in this offering, you will incur an immediate dilution of $2.03 (or 75%) in net tangible book value per share of common stock purchased or issuable upon conversion of the Preferred Stock, based on an assumed public offering price of $2.70 per share of common stock (the last reported sales price of our common stock on March 18, 2013) and $2,700 per share of Preferred Stock. These amounts do not include any additional shares of common stock that we would be required to issue to the investors in our March 31, 2011 financing in the event that the actual offering price in this offering is below $6.00 per share for the common stock and $6,000 per share for the Preferred Stock. Based on an assumed offering price of $2.70 per share of common stock (which is the last reported sales price of our common stock on March 18, 2013) and $2,700 per share of Preferred Stock, we would be required to issue 460,943 additional shares of common stock to our March 31, 2011 investors. See Risk Factors Risks Related to Our Organization, Our Securities and This

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Offering Should we issue shares of common stock in this offering below $6.00 per share and/or shares of Preferred Stock in this offering below $6,000 per share, it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing. The exercise of outstanding warrants and options may result in further dilution of your investment, but only if the public offering price is greater than the per share exercise price of such warrants and options. In addition, if we raise funds by issuing additional shares or convertible securities in the future, the newly issued shares may further dilute your ownership interest.

We may apply the proceeds of this offering to uses that ultimately do not improve our operating results or increase the value of your investment.

We intend to use the net proceeds of this offering to support the worldwide commercialization of MGuard in acute myocardial infarction and pursue U.S. Food and Drug Administration approval, to redeem our convertible debentures and for general corporate purposes. Depending on several factors, including the availability of alternate sources of capital and the possibility that the execution or timing of our business plans may change, management may use these proceeds in a manner different than originally intended. These proceeds could be applied in ways that do not improve our operating results or otherwise increase the value of your investment.

We are subject to financial reporting and other requirements that place significant demands on our resources.

On March 31, 2011, we became subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting and to obtain a report by our independent auditors addressing these assessments. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify of material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of

the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

There are inherent limitations in all control systems, and misstatements dueto error or fraud may occur and not be d

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In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or equity markets for capital.

Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock has been and is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

technological innovations or new products and services by us or our competitors;
additions or departures of key personnel;
sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;
limited availability of freely-tradable unrestricted shares of our common stock to satisfy purchase orders and demand;
our ability to execute our business plan;
operating results that fall below expectations;
loss of any strategic relationship;
industry developments;
economic and other external factors; and
period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock.

There has been a limited market for our common stock and we cannot ensure investors that an active market for our common stock will be sustained.

There has been limited trading in our common stock and there can be no assurance that an active trading market in our common stock will be maintained. Due to the illiquidity, the market price may not accurately reflect our relative value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. Because our common stock is so thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price and investors may not be able to liquidate their investment in us at all or at a price that reflects the value of the business.

In addition, our common stock currently trades on the OTC Bulletin Board, which generally lacks the liquidity, research coverage and i