InspireMD, Inc.
Form S-1/A
November 09, 2012

As filed with the Securities and Exchange Commission on November 9, 2012

File No. 333-184066

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

AMENDMENT NO. 2 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)

Ofir Paz
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:

Rick A. Werner, Esq.
Haynes and Boone, LLP
30 Rockefeller Plaza, 26th Floor
New York, New York 10112
Tel. (212) 659-7300
Fax (212) 884-8234

Yvan-Claude J. Pierre, Esq.
Jodi L. Lashin, Esq.
Reed Smith LLP
599 Lexington Avenue, 22 nd Floor
New York, New York 10022
Tel. (212) 521-5400
Fax (212) 521-5450

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. o

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
Non-accelerated filer o
(Do not check if a smaller reporting company)

Accelerated filer x

Smaller reporting company o

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.

TABLE OF CONTENTS

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 November 9, 2012**

7,246,377 Shares

Common Stock

We are offering 7,246,377 shares of our common stock. Our common stock is quoted on the OTC Bulletin Board under the symbol NSPR. On November 6, 2012, the last reported sale price of our common stock was $5.52 per share, as adjusted for the one-for-four reverse stock split that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

We have applied to list our shares of common stock on the Nasdaq Capital Market under the symbol NSPR.

Our business and an investment in our common 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	$	$
Underwriting discount[(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 1,086,957 shares (based on an assumed offering price of $5.52 per share, which is the last reported sales price of our common stock on November 6, 2012, as adjusted for the one-for-four reverse stock split described above) 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 , 2012.

Cowen and Company

JMP Securities

, 2012

TABLE OF CONTENTS

TABLE OF CONTENTS

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 is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part, other than share and per share information in our consolidated financial statements and the related notes thereto included in this prospectus.

TABLE OF CONTENTS

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 common stock. You should carefully read the prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, 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 exchang transactions 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 is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part, other than share and per share information in our consolidated financial statements and the related notes thereto included in this prospectus.

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 $7.5 million during the three months ended September 30, 2012, a net loss of approximately $7.1 million during the six months 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, and 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. We recently submitted an application to the U.S. Food and Drug Administration to

TABLE OF CONTENTS

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 application was denied due to numerous deficiencies. However, we are currently in discussion with the U.S. Food and Drug Administration in order to resolve the cited deficiencies and create a new trial design that is acceptable to 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 three months ended September 30, 2012, our total revenue was approximately $0.5 million and our net loss was approximately $7.5 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.

We anticipate that in the near term, Ofir Paz will resign from his position as our chief executive officer. Mr. Paz intends to remain in his position while we conduct a thorough search for an appropriate replacement. We have retained a search firm to assist in this process. Mr. Paz s resignation reflects our transition from a private medical device start-up company with a promising new technology to a publicly traded company with a successfully tested, commercialized, CE Mark approved product. After his resignation, we anticipate that Mr. Paz will remain one of our directors and maintain his involvement with us, as necessary, on a consulting basis.

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.

TABLE OF CONTENTS

On October 31, 2011, our stockholders authorized our board of directors to amend our amended and restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, at any time prior to our 2012 annual stockholders meeting, the exact ratio of the reverse stock split to be determined by the board. As of the date of this prospectus, we have not effected the reverse stock split. We intend to effectuate a one-for-four reverse stock split in order to comply with the listing requirements of the Nasdaq Capital Market. The reverse stock split is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part. Such reverse stock split would immediately increase our stock price. In addition, such reverse stock split would reduce the number of shares of common stock outstanding and may affect the liquidity of our common stock.

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 2011 MEDTECH OUTLOOK produced on January 3, 2011 by the Bank of Montreal Investment Banking Group, known as BMO Capital Markets, after registering a compounded annual growth rate from 2002 to 2009 of approximately 13%, revenues from the global coronary stent market is predicted to remain relatively constant, 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 2011 MEDTECH OUTLOOK produced by the BMO Capital Markets on January 3, 2011, the percutaneous coronary intervention procedures involving stents are increasingly being used to treat coronary artery diseases with an 88.3% penetration rate in 2009.

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 and 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), 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 lower rates of 30 day and 1 year major adverse cardiac events 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.

TABLE OF CONTENTS

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 myocardial blush grade 3 levels and 30-day and 1-year major adverse cardiac event rates 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 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. 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. 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).

MGuard Peripheral Applications 14

TABLE OF CONTENTS

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 plus 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	CQ4-2015	2016
MGuard Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	CQ1-2011	CQ1-2013	To be determined	To be determined	To be determined
MGuard Carotid Plus Bio-Stable Mesh	Carotid Arteries	CQ1-2011	CQ1-2013	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, we have determined that the expected commencement of sales in the European Union cannot be accurately predicted since we have delayed the development of this product until additional funding for its 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, Belgium, the 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 peripheral and carotid, for which we expect to have CE Mark approval by the first calendar quarter of 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

TABLE OF CONTENTS

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. We believe these individuals, once convinced of the MGuard Coronary 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. Dr. Gregg W. Stone, director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy of New York Presbyterian Hospital/Columbia University Medical Center and the co-director of Medical Research and Education at The Cardiovascular Research Foundation is the study chairman for the MASTER Trial. Dr. Donald Cutlip, Executive Director of Clinical Investigation at the Harvard Clinical Research Institute, will provide scientific leadership of the U.S. Food and Drug Administration trials and Dr. Stone will act as principal investigator. On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled MASTER II MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction on our behalf. We will pay Harvard Clinical Research Institute, Inc, Cardio Research Foundations (CRF), as a core laboratory, and MedPass International, as our European monitoring group, an estimated aggregate fee of approximately $15 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

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 each of the United States, South Africa and China 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;

TABLE OF CONTENTS

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;
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.

TABLE OF CONTENTS

The Offering[1]

Common stock offered by the Company:	7,246,377 shares (or 8,333,334 shares if the underwriters exercise in full their overallotment option to purchase additional shares)[2]
Common stock to be outstanding after this offering:	25,090,121 shares (or 26,177,078 shares if the underwriters exercise in full their overallotment option to purchase additional shares)[2]
Use of proceeds:	We intend to use the net proceeds of this offering to support the worldwide commercialization of MGuard in acute myocardial infarction and pursue FDA approval in the United States, to redeem our convertible debentures 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 shares of our common stock.
OTC Bulletin Board symbol:	NSPR
Proposed symbol and listing:	We have applied for to list our shares of common stock on the Nasdaq Capital Market under the symbol NSPR.

(1) All share amounts are adjusted for the anticipated one-for-four reverse stock split that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

The number of shares of common stock outstanding after this offering is based on 17,843,744 shares outstanding on November 6, 2012 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;
57,976 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $4.93 per share;
1,750,510 shares of common stock issuable upon the conversion of our senior secured convertible debentures due April 5, 2014;
3,024,010 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.004 to $10.40 and having a weighted average exercise price of $4.68 per share; and
1,685,636 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan.

Unless otherwise stated, all information contained in this prospectus assumes:

no exercise of the overallotment option granted to the underwriters; and

other than share and per share information in our consolidated financial statements and the related notes thereto, a one-for-four reverse stock split in order to comply with the listing requirements of

TABLE OF CONTENTS

the Nasdaq Capital Market. Such reverse stock split would immediately increase our stock price. In addition, such reverse stock split would reduce the number of shares of common stock outstanding and may affect the liquidity of our common stock. The reverse stock split is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

(2) Based on an assumed offering price of $5.52 per share (which is the last reported sales price of our common stock on November 6, 2012, as adjusted for the one-for-four reverse stock split described above). In addition, these share amounts do not take into account the issuance of any additional shares of common stock to the investors in our March 31, 2011 financing that would result in the event that the actual offering price in this offering is below $6.00 per share. Based on the assumed offering price of $5.52 per share, we would be required to issue 46,521 additional shares to these investors. See Risks Related to Our Organization, Our Common Stock and This Offering Should we issue shares in this offering at a price below $6.00 per share it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing.

TABLE OF CONTENTS

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 September 30, 2012 and the statement of operations data for the three months ended September 30, 2012 and 2011 have been derived from the unaudited consolidated financial statements for such periods, included in this prospectus.

The historical share and per share amounts set forth below reflect the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

Summary of Operations Data

	Six Months Ended June 30, 2012	Year Ended December 31, 2011	2010	2009	Three Months Ended September 30, 2012 (unaudited)	2011 (unaudited)
	(amounts in thousands, except per share and percentage data)					
Revenues	$2,071	$6,004	$4,949	$3,411	$509	$1,986
Cost of revenues	$1,377	$3,011	$2,696	$2,291	$230	$801
Gross profit (loss)	$694	$2,993	$2,253	$1,120	$279	$1,185
Gross margin	34 %	50 %	46 %	33 %	55 %	60 %
Total operating expenses	$7,852	$16,722	$5,472	$3,837	$3,560	$3,335
Net loss	$(7,081)	$(14,665)	$(3,420)	$(2,724)	$(7,506)	$(2,283)
Net loss per share basic and diluted	$(0.42)	$(0.95)	$(0.28)	$(0.23)	$(0.44)	$(0.14)
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	17,074,235	16,075,171
As adjusted[1] net loss per share basic and diluted (Unaudited)	$(0.74)	$(0.95)	$(0.28)	$(0.23)	$(0.34)	$(0.14)
As adjusted[1] weighted average	18,153,118	15,359,925	12,308,632	11,914,713	19,448,580	16,075,171

number of ordinary shares used computing net loss per share basic and diluted (Unaudited)

(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.

TABLE OF CONTENTS

Balance Sheet Data

	September 30, 2012 (unaudited)	
	Actual	As adjusted[1]
Cash and cash equivalents	$ 8,297	$ 31,891
Restricted cash	$ 37	$ 37
Working capital[2]	$ 8,611	$ 32,205
Total assets	$ 13,615	$ 36,335
Long-term liabilities	$ 11,008	$ 5,373
Equity (capital deficiency)	$ (756)	$ 27,598

(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.

TABLE OF CONTENTS

RISK FACTORS

Investing in our common stock 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 shares of our common stock. 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 common stock could decline, and you could lose all or part of your investment in our common stock.

Risks Related to Our Business

The report of our independent registered public accounting firm 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 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, this 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,

TABLE OF CONTENTS

patents that may be issued to us now or in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the 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.

TABLE OF CONTENTS

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 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 produce our MGuard stent in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our MGuard stent and 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. 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 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

TABLE OF CONTENTS

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 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.

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

Physicians may not widely adopt the MGuard stent unless they determine,based on experience, long-term clinical c

TABLE OF CONTENTS

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 per-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 9 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 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

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

TABLE OF CONTENTS

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 constitutes 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 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.

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

TABLE OF CONTENTS

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 service 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 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.

We may become subject to claims by much larger and better capitalizedcompetitors seeking to invalidate our intelle

TABLE OF CONTENTS

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.

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.

TABLE OF CONTENTS

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 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

If we fail to obtain an adequate level of reimbursement for our products bythird party payors, there may be no comm

TABLE OF CONTENTS

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, 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 Health Care and Educational 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 does levy a 2.3% excise tax on all U.S. medical device sales beginning in 2013. 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 starting 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.

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 our management 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

TABLE OF CONTENTS

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 5 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 not likely that we will be subject to fines or other penalties on an individual or company level.

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 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, 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.

Any additional capital raised through the sale of equity or equity backed securities may dilute 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

TABLE OF CONTENTS

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, 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 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 Defence 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 anticipate being subject to fluctuations in currency exchange ratesbecause we expect a substantial portion of ou

Our operations could be disrupted as a result of the obligation of certain ofour personnel residing in Israel to perform

TABLE OF CONTENTS

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

We have non-competition agreements with all of our employees, all 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 all 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. Inspire 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 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 and was increased to 25% in 2012. 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.

The tax benefits that are available to us require us to continue meetingvarious conditions and may be terminated or

TABLE OF CONTENTS

Risks Related to Our Organization, Our Common Stock and This Offering

Should we issue shares in this offering at a price below $6.00 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 per share (as adjusted for the anticipated one-for-four reverse stock split of our common stock), 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 issue 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 issue plus (2) the number of such additional shares of common stock so issued. 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, 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, 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 $5.52 per share (which is the last reported sales price of the Company s common stock on November 6, 2012, as adjusted for the one-for-four reverse stock split that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part), we would be required to issue 46,521 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 common stock in this offering, you will incur an immediate dilution of $4.39 (or 80%) in net tangible book value per share from the price you paid, based on an assumed public offering price of $5.52 per share (the last reported sales price of our common stock on November 6, 2012, as adjusted for the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part). 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 FDA approval in the United States, 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.

TABLE OF CONTENTS

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.

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;

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

our ability to execute our business plan;
operating results that fall below expectations;

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

TABLE OF CONTENTS

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. If our common stock is 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 institutional investor following of a national securities exchange like the NYSE MKT, the New York Stock Exchange or the Nasdaq Capital Market. While we have applied to list our common stock on the Nasdaq Capital Market, there can be no assurance that trading of our common stock on such market will be sustained or desirable.

Delaware law and our corporate charter and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. As of November 6, 2012, there were 4,399,698 shares of our common stock issuable upon the conversion of our outstanding convertible debentures and the exercise of our outstanding warrants, all of which are currently registered for resale. In addition, there are 17,235,694 shares of our common stock currently saleable under Rule 144. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

In addition, the fact that our stockholders, warrant holders and debenture holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and

TABLE OF CONTENTS

economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

Risks Related to our Convertible Debentures

Our obligations to the holders of our convertible debentures are secured by all of our assets, so if we default on those obligations, the convertible debenture holders could foreclose on our assets.

The holders of our convertible debentures have a security interest in all of our assets and those of our subsidiaries. As a result, if we default under our obligations to the convertible debenture holders, the convertible debenture holders could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

Our convertible debentures and the associated securities purchase agreement contain covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

The terms of our convertible debentures could have negative consequences to us, such as:

we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;

we may be unable to refinance our indebtedness on terms acceptable to us, or at all; and

we may be more vulnerable to economic downturns and limit our ability to withstand competitive pressures.

Additionally, covenants in our convertible debentures and the associated securities purchase agreement impose operating and financial restrictions on us. These restrictions prohibit or limit our ability, and the ability of our subsidiaries, to, among other things:

pay cash dividends to our stockholders;

redeem, repurchase or otherwise acquire more than a de minimis number of shares of our common stock or common stock equivalents;

incur additional indebtedness;

permit liens on assets or conduct sales of assets;

effectuate stock splits until April 5, 2013, except in connection with an initial listing on a national securities exchange or to meet the continued listing requirements of such exchange;

cease making public filings under the Securities Exchange Act of 1934, as amended;

engage in transactions with affiliates; and

amend our charter documents in a way that would materially and adversely affect any holder of our convertible debentures.

These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities. Moreover, additional debt financing we may seek may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

We do not expect to pay dividends in the future. As a result, any return oninvestment may be limited to the value of

The conversion of our convertible debentures and the exercise of the warrants issued to the purchasers of our convertible debentures would have a dilutive impact on our existing stockholders.

As of November 6, 2012, there were 1,750,510 shares of common stock underlying our convertible debentures and 913,944 shares of common stock underlying warrants that were issued to purchasers and placement agents in connection with the issuance of the convertible debentures, for a total of 2,664,454 shares of common stock (as adjusted for the anticipated one-for-four reverse stock split of our common stock that is

TABLE OF CONTENTS

expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part). If and when issued, these additional 2,664,454 shares of common stock will equal approximately 9.6% of our then outstanding shares of common stock (assuming an offering price of $5.52, the last reported sales price of our common stock on November 6, 2012, as adjusted for the anticipated one-for-four reverse stock split of our common stock, but not taking into account the issuance of 46,521 additional shares of common stock to the investors in our March 31, 2011 financing that would result based on the assumed offering price of $5.52 per share, and would immediately dilute our current stockholders in terms of ownership percentage and voting power. The terms of the convertible debentures and related warrants contain provisions that restrict the amount of shares a holder can receive upon conversion or exercise to 4.99% of the then outstanding number of shares of our common stock. However, these restrictions do not prevent the holders from selling some of their holdings and then receiving additional shares. In this way, the holders could sell more than these limits while never holding more than the limits. As a result, even with the restrictions, the holders of these convertible debentures and warrants could ultimately convert and exercise, and then sell, the full amount issuable upon conversion and exercise of the convertible debentures and warrants, respectively, in which case our current stockholders would suffer the full amount of dilution.

The holders of our convertible debentures might be able to exert substantial influence over us in the event that Sol J. Barer, Ph.D. ceases to remain our chairman.

Under the terms of the securities purchase agreement pursuant to which our convertible debentures were sold, if Sol J. Barer, Ph.D. ceases to serve as our chairman due to Dr. Barer s resignation following a material adverse change to the condition of Dr. Barer or any member of Dr. Barer s immediate family or the vote or written consent of independent stockholders, we would be required to appoint two persons to our board of directors designated by Genesis Capital Advisors LLC, the investment advisor to our lead investors in the convertible debenture offering, and support the election of such persons until the convertible debentures are either repaid or converted in full. In addition, in the event that Dr. Barer ceases to serve as our chairman for any other reason while the convertible debentures are outstanding, it would be an event of default under the convertible debentures, which could result in the acceleration of our convertible debentures at the election of the holders of 60% of the outstanding principal of the convertible debentures, an amount that Genesis Capital Advisors LLC presently controls. As a result, Genesis Capital Advisors LLC, or its assigns, have the potential to exert substantial influence over our management and governance in the event Dr. Barer ceases to serve as our chairman and they may exert such influence in a manner that is not consistent with the best interests of our common stockholders.

We may default upon our obligations under our convertible debentures.

The holders of our convertible debentures may require us to redeem our convertible debentures after October 5, 2013 or upon the occurrence of an event of a default under our convertible debentures for 112% of the then outstanding principal amount, plus all accrued interest. In the event that we are required to redeem some or all of our convertible debentures, we may not have sufficient resources to do so and we may have to seek additional debt or equity financing to cover the costs of redeeming our convertible debentures. Any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. Because our obligations under our convertible debentures are secured by a security interest in substantially all of our assets and properties, if we cannot repay our obligations under our convertible debentures, the holders of our convertible debentures may have claims against, and ultimately may foreclose upon and take possession of, substantially all of our assets and properties. In such an event, the holders of our convertible debentures would have control of us.

Risks Related to Our Intended Reverse Stock Split

There can be no assurance that we will be able to meet all of the requirements for listing our common stock on any national securities exchange or to meet the continued listing standards of any national securities exchange after a reverse stock split.

Each national securities exchange has numerous initial listing requirements applicable to the listing of our common stock and its continued listing thereafter. We cannot assure you that our common stock will be accepted for listing on the Nasdaq Capital Market or any other national securities exchange following the

TABLE OF CONTENTS

reverse stock split or that we will maintain compliance with all of the requirements for our common stock to remain listed. Moreover, there can be no assurance that the market price of our common stock after the reverse stock split will adjust to reflect the decrease in common stock outstanding or that the market price following a reverse stock split will either exceed or remain in excess of the current market price.

If the reverse stock split is implemented, the resulting per-share price may not attract institutional investors, investment funds or brokers and may not satisfy the investing guidelines of these investors or brokers, and consequently, the trading liquidity of common stock may not improve.

While we believe that a higher share price may help generate investor and broker interest in our common stock, the reverse stock split may not result in a share price that will attract institutional investors or investment funds or satisfy the investing guidelines of institutional investors, investment funds or brokers. A decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of the reverse stock split. If the reverse stock split is implemented and the market price of our common stock declines, the percentage decline may be greater than would occur in the absence of the reverse stock split. The market price of our common stock is also based on our performance and other factors, which are unrelated to the number of shares of common stock outstanding.

There can be no assurance that we will be able to meet all of the requirementsfor listing our common stock on any

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as may, should, could, would, predicts, potential, continue, expects, anticipates, future, intends, plans, believes, expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

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;

disputes over ownership of intellectual property;

accusations of infringement or violation of third party intellectual property;

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;

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.

You should review carefully the section entitled Risk Factors beginning on page 12 of this prospectus for a discussion of these and other risks that relate to our business and investing in shares of our common stock. The forward-looking statements contained in this prospectus are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

TABLE OF CONTENTS

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately $36.6 million. If the underwriters fully exercise the overallotment option, the total net proceeds of the shares we sell will be approximately $42.2 million. Net proceeds is what we expect to receive after paying the underwriting discount and other expenses of the offering.

We intend to use the net proceeds as follows:

We expect to use approximately $23.5 million to support the worldwide commercialization of MGuard Coronary in acute myocardial infarction. This is expected to include expanding our manufacturing capability, building our sales and marketing capacity, completing clinical trials and obtaining necessary government approvals, including FDA approval in the United States.

We expect to use approximately $13.1 million to redeem our convertible debentures due April 5, 2014, which bear interest at an annual rate of 8% and may be redeemed for a price equal to 112% of the amount of principal to be redeemed plus all accrued but unpaid interest and other amounts due thereunder. The proceeds from the convertible debentures were used to support the commercialization of MGuard Coronary, including sales and marketing efforts, our MASTER Trial and FDA trial and as working capital.

Any balance of the net proceeds will be used for general corporate purposes, including the development of future products.

Investors are cautioned, however, that expenditures may vary substantially from these estimates. Investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, the amount of competition and other operational factors. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

From time to time, we evaluate these and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized. Circumstances that may give rise to a change in the use of proceeds include:

- a change in development plan or strategy;
- the addition of new products or applications;
- technical delays;
- delays or difficulties with our clinical trials;
- negative results from our clinical trials;
- failure to achieve sales as anticipated; and
- the availability of other sources of cash including cash flow from operations and new bank debt financing arrangements, if any.

Until we use the net proceeds of this offering, we will invest the funds in short-term, investment grade, interest-bearing securities.

TABLE OF CONTENTS

MARKET FOR OUR COMMON STOCK

Our common stock has been quoted on the OTC Bulletin Board since April 11, 2011 under the symbol NSPR. Prior to that date, there was no active market for our common stock. The following table sets forth the high and low bid prices for our common stock for the periods indicated, as reported by the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. The quotations are adjusted for the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

Fiscal Year Ending June 30, 2013	High	Low
First Quarter	$ 10.00	$ 3.84
Second Quarter (through November 6, 2012)	$ 10.16	$ 5.40

Transition Period Ended June 30, 2012	High	Low
First Quarter	$ 8.60	$ 4.40
Second Quarter	$ 7.40	$ 2.40

Fiscal Year Ended December 31, 2011	High	Low
Second Quarter	$ 11.56	$ 7.00
Third Quarter	$ 10.96	$ 7.20
Fourth Quarter	$ 10.36	$ 6.40

The last reported sales price of our common stock on the OTC Bulletin Board on November 6, 2012, was $5.52 per share, as adjusted for the anticipated one-for-four reverse stock split of our common stock. As of November 6, 2012, there were approximately 192 holders of record of our common stock.

We intend to effectuate a one-for-four reverse stock split in order to comply with the listing requirements of the Nasdaq Capital Market that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part. Such reverse stock split would immediately increase our stock price. In addition, such reverse stock split would reduce the number of shares of common stock outstanding and may affect the liquidity of our common stock.

DIVIDEND POLICY

In the past, we have not declared or paid cash dividends on our common stock, and we do not intend to pay any cash dividends on our common stock. Rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

TABLE OF CONTENTS

CAPITALIZATION

The following table summarizes our cash and cash equivalents, certain other items from our historical consolidated balance sheet, and capitalization as of September 30, 2012:

on an actual basis; and

on an unaudited as adjusted basis, giving effect to (1) the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part and (2) 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.

For the purposes of the Capitalization discussion, we determined the assumed number of shares by dividing (x) $40,000,000 that we anticipate raising in this offering (excluding any shares sold pursuant to the underwriters overallotment option), by (y) an assumed offering price of $5.52 per share, which is the last reported sales price of our common stock on November 6, 2012 (after giving effect to the anticipated one-for-four reverse stock split discussed above). The actual number of shares sold in this offering will be determined by dividing (x) $40,000,000 by (y) the public offering price as mutually determined by the underwriters and us. In addition, for purposes of this Capitalization discussion, we did not take into account the issuance of any additional shares of common stock to the investors in our March 31, 2011 financing that would result in the event that the actual offering price in this offering is below $6.00 per share. Based on the assumed offering price of $5.52 per share, we would be required to issue 46,521 additional shares to these investors. See Risks Related to Our Organization, Our Common Stock and This Offering Should we issue shares in this offering at a price below $6.00 per share it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing.

	September 30, 2012 (unaudited)	
	Actual	As Adjusted
Cash and cash equivalents	8,297	31,891
Convertible loan	5,635	
Deferred debt issuance costs	874	
Equity (capital deficiency):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 17,149,225 and 24,395,603 shares issued and outstanding at September 30, 2012, actual and as adjusted, respectively	7	10
Preferred stock, par value $0.0001 per share; 5,000,000 shares authorized; none issued and outstanding at September 30, 2012		
Additional paid-in capital	50,464	83,371
Accumulated deficit	(51,227)	(55,783)
Total equity (capital deficiency)	(756)	27,598

Each $1.00 increase (decrease) in the assumed offering price would increase (decrease) our pro forma net tangible book value per share after this offering by $0.05 per share and the dilution in pro forma net tangible book value to new investors in this offering by $0.95 per share, assuming that the aggregate offering price, as set forth on the cover page of this prospectus, remains the same.

34

TABLE OF CONTENTS

DILUTION

The discussion assumes an offering price of $5.52 per share, which is the last reported sales price of our common stock on November 6, 2012, as adjusted for the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

Our net tangible book value on September 30, 2012 was approximately $(0.8) million, or $(0.04) per share. Net tangible book value is total assets minus the sum of liabilities and intangible assets. Net tangible book value per share is net tangible book value divided by the total number of shares outstanding.

After giving effect to adjustments relating to the offering, our pro forma net tangible book value on September 30, 2012, would have been $27.6 million, or $1.13 per share. The adjustments made to determine pro forma net tangible book value per share are the following:

An increase in total assets to reflect the net proceeds of the offering as described under Use of Proceeds.
The addition of the number of shares offered by this prospectus to the number of shares outstanding.
The following table illustrates the pro forma increase in net tangible book value of $1.17 per share and the dilution (the difference between the offering price per share and net tangible book value per share) to new investors:

Assumed Public offering price per share	$5.52
Net tangible book value per share as of September 30, 2012	$(0.04)
Increase in net tangible book value per share attributable to the offering	$1.17
Pro forma net tangible book value per share as of September 30, 2012 after giving effect to the offering	$1.13
Dilution per share to new investors in the offering	$4.39

The following table shows the difference between existing stockholders and new investors with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders	17,149,226	70 %	$ 27,464,574	41 %	$ 1.60
New shareholders	7,246,377	30 %	$ 40,000,000	59 %	$ 5.52
Total	24,395,603	100 %	$ 67,464,574	100 %	$ 2.77

The foregoing tables and calculations are based on the number of shares of our common stock outstanding as of September 30, 2012 and exclude:

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;
179,878 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $4.93 per share;

1,736,953 shares of common stock issuable upon the conversion of our senior secured convertible debentures due April 5, 2014;

3,404,283 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.004 to $10.40 and having a weighted average exercise price of $4.20 per share;

1,305,363 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 in this offering is below $6.00 per share. Based on an assumed offering price of $5.52 per share (which is the last reported sales

TABLE OF CONTENTS

price of the Company s common stock on November 6, 2012, as adjusted for the one-for-four reverse stock split that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part), we would be required to issue 46,521 additional shares to these investors. See Risks Related to Our Organization, Our Common Stock and This Offering Should we issue shares in this offering at a price below $6.00 per share it will result in the issuance of additional shares, without any new consideration, to the investors in our March 31, 2011 financing.

TABLE OF CONTENTS

SELECTED FINANCIAL INFORMATION AND OTHER DATA

The following selected 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 December 31, 2011 and 2010 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, 2009 has been derived from audited consolidated financial statements not included in this prospectus. The balance sheet data at December 31, 2008 and 2007, and the statement of operations data for each of the years ended December 31, 2008 and 2007, have been derived from our books and records. The balance sheet data at September 30, 2012 and the statement of operations data for the three months ended September 30, 2012 and 2011 have been derived from the unaudited consolidated financial statements for such periods, included in this prospectus.

The share and per share amounts set forth below reflect the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

Summary of Operations Data

TABLE OF CONTENTS

Balance Sheet Data

	December 31,						September 30,
	June 30, 2012	2011	2010	2009	2008	2007	2012 (unaudited)
	(in thousands)						
Cash and cash equivalents	$10,284	$5,094	$636	$376	$1,571	$2,717	$8,297
Restricted cash	$37	$91	$250	$302	$30	$34	$37
Working capital[(1)]	$10,759	$6,389	$(53)	$(1,289)	$589	$2,625	$8,611
Total assets	$16,014	$10,465	$4,355	$4,509	$4,448	$3,923	$13,615
Long-term liabilities	$7,078	$270	$1,325	$484	$898	$87	$11,008
Equity (capital deficiency)	$5,386	$6,754	$(914)	$(1,339)	$134	$2,949	$(756)

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

SELECTED QUARTERLY FINANCIAL DATA

The following selected quarterly consolidated unaudited 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 following table sets forth selected financial information for the dates and periods indicated. Our results for any of these periods are not necessarily indicative of the results to be expected for the year ending June 30, 2013 or for any other future period.

The share and per share amounts set forth below reflect the anticipated one-for-four reverse stock split of our common stock that is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

	Fiscal Year Ending June 30, 2013 First Quarter (unaudited) (in thousands, except per share and percentage data)	
Revenues	$ 509	
Cost of revenues	$ 230	
Gross profit (loss)	$ 279	
Gross margin	55	%
Total operating expenses	$ 3,560	
Net loss	$ (7,506)	
Basic and diluted loss per common share	$ (0.44)	
Basic and diluted common shares outstanding	17,074,235	

	Six Months Ended June 30, 2012		
	Quarter Ended March 31, 2012	Quarter Ended June 30, 2012	
	(unaudited)		
	(in thousands, except per share and percentage data)		
Revenues	$ 1,138	$ 933	
Cost of revenues	$ 574	$ 803	
Gross profit (loss)	$ 564	$ 130	
Gross margin	50	%	14	%
Total operating expenses	$ 3,690	$ 4,162	
Net loss	$ (3,140)	$ (3,941)	
Basic and diluted loss per common share	$ (0.18)	$ (0.23)	
Basic and diluted common shares outstanding	17,044,737	17,043,704	

TABLE OF CONTENTS

	Fiscal Year Ended December 31, 2011			
	First Quarter (unaudited)	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share and percentage data)			
Revenues	$1,686	$1,040	$1,986	$1,292
Cost of revenues	$899	$640	$801	$671
Gross profit (loss)	$787	$400	$1,185	$621
Gross margin	47 %	38 %	60 %	48 %
Total operating expenses	$1,957	$2,572	$3,335	$8,858
Net loss	$(1,895)	$(2,254)	$(2,283)	$(8,233)
Basic and diluted loss per common share	$(0.15)	$(0.14)	$(0.14)	$(0.49)
Basic and diluted common shares outstanding	12,699,725	15,983,565	16,075,171	16,674,356

	Fiscal Year Ended December 31, 2010			
	First Quarter (unaudited)	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share and percentage data)			
Revenues	$2,097	$908	$1,223	$721
Cost of revenues	$1,337	$479	$561	$319
Gross profit (loss)	$760	$429	$662	$402
Gross margin	36 %	47 %	54 %	56 %
Total operating expenses	$1,404	$1,118	$1,379	$1,571
Net loss	$(729)	$(663)	$(847)	$(1,181)
Basic and diluted loss per common share	$(0.06)	$(0.05)	$(0.07)	$(0.10)
Basic and diluted common shares outstanding	12,148,810	12,278,366	12,372,615	12,420,054

39

TABLE OF CONTENTS

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations in conjunction with the Selected Financial Information and Other Data, Selected Quarterly Financial Data and our consolidated financial statements and the related notes thereto included elsewhere in this prospectus. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under Risk Factors and elsewhere in this prospectus. See Special Note Regarding Forward-Looking Statements included elsewhere in this prospectus.

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. 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).

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we acquired all of the capital stock of InspireMD Ltd., a company formed under the laws of the State of Israel, in exchange for an aggregate of 12,666,665 (as adjusted for the anticipated one-for-four reverse stock split of our common stock) shares of our common stock. As a result of these share exchange transactions, InspireMD Ltd. became our wholly-owned subsidiary, we discontinued our former business and succeeded to the business of InspireMD Ltd. as our sole line of business.

The share exchange transactions were accounted for as a recapitalization. InspireMD Ltd. is the acquirer for accounting purposes and we are the acquired company. Accordingly, the historical financial statements presented and the discussion of financial condition and results of operations herein are those of InspireMD Ltd., retroactively restated for, and giving effect to, the number of shares received in the share exchange transactions, and do not include the historical financial results of our former business. The accumulated earnings of InspireMD Ltd. were also carried forward after the share exchange transactions and earnings per share have been retroactively restated to give effect to the recapitalization for all periods presented. Operations reported for periods prior to the share exchange transactions are those of InspireMD Ltd.

On October 31, 2011, our stockholders authorized our board of directors to amend our amended and restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, at any time prior to our 2012 annual stockholders meeting, the exact ratio of the reverse stock split to be determined by the board. We intend to effectuate a one-for-four reverse stock split in order to comply with the listing requirements of Nasdaq Capital Market. Such reverse stock split would immediately increase our stock price. In addition, such reverse stock split would reduce the number of shares of common stock outstanding and may affect the liquidity of our common stock. The reverse stock split is expected to occur the day immediately following the effectiveness of the registration statement of which this prospectus is a part.

Recent Developments

During the past several months, we have been realigning our distributor relationships in anticipation of results from our MASTER Trial, which were published on October 24, 2012. The MASTER trial is the first major randomized study comparing the MGuard Coronary to commercially-approved bare metal or drug-eluting stents in primary angioplasty for the treatment of acute STEMI, the most severe form of heart attack. As such, we are in the process of appointing new distributors in certain territories, and believe that new incentives and broader responsibilities have strengthened arrangements with our best and most experienced country and regional partners. Third party distributors are also being replaced by direct sales channels in key European countries where end user average selling prices and the lack of strong distributors are limiting factors. These activities caused our sales for the three months ended September 30, 2012 to decrease to approximately $0.5 million, as compared to $2.0 million during the same period in 2011.

TABLE OF CONTENTS

Critical Accounting Policies

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory write-off, provisions for returns, legal contingencies, estimation of the fair value of share-based compensation and estimation of the fair value of warrants.

Functional currency

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ($ or dollar). Accordingly, the functional currency of us and of our subsidiaries is the dollar.

The dollar figures are determined as follows: transactions and balances originally denominated in dollars are presented in their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. The resulting translation gains or losses are recorded as financial income or expense, as appropriate. For transactions reflected in the statements of operations in foreign currencies, the exchange rates at transaction dates are used. Depreciation and changes in inventories and other changes deriving from non-monetary items are based on historical exchange rates.

Fair value measurement

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

In determining fair value, we use various valuation approaches, including market, income and/or cost approaches. Hierarchy for inputs is used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the reliability of inputs.

Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash, cash equivalents and restricted cash, which are deposited in major financial institutions in the United States, Israel and Germany, and trade accounts receivable. Our trade accounts receivable are derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers financial condition and, generally, require no collateral from our customers. We also have a credit insurance policy for some of our customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We

review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount our management reasonably believes will be collected. To mitigate risks, we deposit cash and cash equivalents with high credit quality financial institutions. Provisions for doubtful debts are netted against Accounts receivable-trade.

Inventory

Inventories include finished goods, work in process and raw materials. Inventories are stated at the lower of cost (cost is determined on a first-in, first-out basis) or market value. Our inventories generally have a

TABLE OF CONTENTS

limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, in our opinion, factors indicate that impairment has occurred, we establish a reserve against the inventories carrying value. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of our inventories and reported operating results. With respect to inventory on consignment, see Revenue recognition below.

Revenue recognition

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer, collection is reasonably assured and product returns can be reliably estimated. When product returns can be reliably estimated a provision is recorded, based on historical experience, and deducted from revenues. The provision for sales returns and related costs are included in Accounts payable and accruals Other under Current liabilities and Inventory on consignment, respectively.

When returns cannot be reliably estimated, both related revenues and costs are deferred, and presented under Deferred revenues and Inventory on consignment, respectively.

As of September 30, 2012, there are no deferred revenues related to sales for which the rate of return cannot be reliably estimated.

Our revenue arrangements may contain delivery of free products upon the achievement of sales targets. Each period, we estimate the amount of free products to which these distributors will be entitled based upon the expected achievement of sales targets and defer a portion of revenues accordingly.

We recognize revenue net of value added tax.

Research and development costs

Research and development costs are charged to the statement of operations as incurred.

Share-based compensation

Employee option awards are classified as equity awards and accounted for using the grant-date fair value method. The fair value of share-based awards is estimated using the Black-Scholes valuation model, which is expensed over the requisite service period, net of estimated forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation expense for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

We account for equity instruments issued to third party service providers (non-employees) by recording the fair value of the options granted using an option pricing model, at each reporting period, until rewards are vested in full. The expense is recognized over the vesting period using the accelerated multiple option approach. The expense relates to options granted to third party service providers with respect to successful investor introductions that are recorded at their fair value in equity, as issuance costs.

In addition, certain of our share-based awards are performance based, i.e., the vesting of these awards depends upon achieving certain goals. We estimate the expected pre-vesting award probability, i.e., the expected likelihood that the performance conditions will be achieved, and only recognize expense for those shares expected to vest.

Uncertain tax and value added tax positions

We follow a two-step approach to recognizing and measuring uncertain tax and value added tax positions. The first step is to evaluate the tax and value added tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax and value added tax benefit as the largest amount that is more than 50% and 75%, respectively, likely of being realized upon ultimate settlement. Such liabilities are classified as long-term,

TABLE OF CONTENTS

unless the liability is expected to be resolved within twelve months from the balance sheet date. Our policy is to include interest and penalties related to unrecognized tax benefits within financial expenses.

Results of Operations

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

Revenue. For the three months ended September 30, 2012, total revenue decreased approximately $1.5 million, or 74.4%, to approximately $0.5 million from approximately $2.0 million during the same period in 2011. The following is an explanation of the approximately $1.5 million decrease in revenue broken down by its main two components, a decrease in gross revenues of approximately $1.6 million, partially offset by a net increase in deferred revenues of approximately $0.1 million.

For the three months ended September 30, 2012, total gross revenue decreased by approximately $1.6 million, or approximately 78.4%, to approximately $0.4 million from approximately $2.0 million during the same period in 2011. This decrease in total gross revenue was predominately sales volume based, with decreased sales volume accounting for approximately $1.5 million, or approximately 76.5%, and price decreases to our repeat distributors accounting for the remaining approximately $0.1 million, or approximately 1.9%. The $1.5 million decrease was attributable primarily to activities in anticipation of the release of our MASTER trail results at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Miami Florida, which included evaluating and appointing new distributors in some territories, as well as replacing third party distributors with direct sales channels in key European countries where end user average selling prices and the lack of strong distributors are limiting current sales. Broken out by individual markets, the decrease in gross revenue was mainly attributable to a decrease of approximately $0.2 million in gross revenue from our distributor in Argentina, a decrease of approximately $0.2 million in gross revenue from our distributor in Brazil, a decrease of approximately $0.2 million in gross revenue from our distributor in Mexico, a decrease of approximately $0.1 million in gross revenue from our distributor in Italy, a decrease of approximately $0.1 million in gross revenue from our distributor in Spain, a decrease of approximately $0.1 million in gross revenue from our distributor in Belarus, a decrease of approximately $0.1 million in gross revenue from our distributor in Russia, a decrease of approximately $0.1 million in gross revenue from our distributor in France, a decrease of approximately $0.1 million in gross revenue from our distributor in Ireland and a net decrease of approximately $0.4 million from our other distributors.

Net deferred revenue recognized during the three months ended September 30, 2012 increased to approximately $0.1 million recognized in revenue from approximately $4,000 deferred during the same period in 2011. This increase was sales volume based, partially offset by approximately $10,000 attributable to price decreases. The deferred revenue recognized and deferred during both periods related to our provision for returns, which is calculated based on our history of returns, and recognized one year later. The reason for the increase in the three months ended September 30, 2012, compared to the same period in 2011, is the decrease in sales between periods, as well as our reassessment of the provision for returns in the three months ended September 30, 2012. Our reassessment of the provision for returns of approximately $55,000 was based on a comparison of our history of returns against the percentage of sales we had been recording in the provision. For the three months ended September 30, 2012, higher sales in the three months ended September 30, 2011, as well as the reassessed provision, caused the recognition of past provision for returns to be higher than the provision recorded relating to sales made during the three months ended September 30, 2012. For the three months ended September 30, 2011, higher sales caused the provision recorded relating to sales made during the three months ended September 30, 2011 to be higher than the recognition of past provision for returns.

Gross Profit. For the three months ended September 30, 2012, gross profit (revenue less cost of revenues) decreased 76.5%, or approximately $0.9 million, to approximately $0.3 million from approximately $1.2 million during the same period in 2011. The key driver of the decrease in gross profit was our decrease in net revenues of approximately $1.5 million, as described above. For the three months ended September 30, 2012, our average selling price per stent recognized in revenue decreased to $569, and we recognized the sale of 826 stents, from an average price of $624 per stent and 3,186 stents recognized in revenue for the same period in 2011. For the three months ended September 30, 2012, our cost of goods sold per stent was $279 per stent recognized in revenue, as compared to $251 per stent recognized in revenue during the same period

TABLE OF CONTENTS

in 2011. Gross margin decreased from 59.7% in the three months ended September 30, 2011 to 54.8% in the three months ended September 30, 2012.

Research and Development Expense. For the three months ended September 30, 2012, research and development expense increased 72.9%, or approximately $0.4 million, to approximately $0.9 million from approximately $0.5 million during the same period in 2011. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.3 million, attributable mainly to the MASTER Trial (approximately $0.2 million), and the MGuard Carotid clinical trial (approximately $0.1 million). In addition to the increase in clinical trial expenses, there was an increase of approximately $0.1 million in salaries and share-based compensation due to our hiring of additional clinical trial personnel. Research and development expense as a percentage of revenue increased to 185.9% for the three months ended September 30, 2012 from 27.5% in the same period in 2011.

Selling and Marketing Expense. For the three months ended September 30, 2012, selling and marketing expense increased 33.1%, or approximately $0.1 million, to approximately $0.4 million, from approximately $0.3 million during the same period in 2011. The increase in selling and marketing expense resulted primarily from approximately $60,000 of additional salaries and approximately $50,000 of additional travel expenses as we expanded our sales activities worldwide. Selling and marketing expense as a percentage of revenue increased to 79.0% in 2012 from 15.2% in 2011.

General and Administrative Expense. For the three months ended September 30, 2012, general and administrative expense decreased 11.0%, or approximately $0.3 million, to approximately $2.2 million from approximately $2.5 million during the same period in 2011. This decrease resulted primarily from a decrease in share-based compensation of $0.8 million (which predominately pertained to directors compensation), partially offset by an increase of approximately $0.2 million in bad debt expense, an increase of approximately $0.1 million in audit fees and an increase of approximately $0.2 million in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 434.6% in 2012 from 125.2% in 2011.

Financial Expenses. For the three months ended September 30, 2012, financial expense increased to approximately $4.2 million from approximately $0.1 million during the same period in 2011. The increase in expense resulted primarily from approximately $3.2 million of financial expense pertaining to the revaluation of warrants due to our stock price increasing to $2.27 on September 30, 2012, from $1.06 on June 30, 2012, and approximately $1.0 million of amortization expense pertaining to the convertible debentures and their related issuance costs for the three months ended September 30, 2012. Financial expense as a percentage of revenue increased from 5.4% in 2011, to 828.7% in 2012.

Tax Expenses. Tax expense remained relatively flat at $7,000 for the three months ended September 30, 2012, as compared to $25,000 during the same period in 2011.

Net Loss. Our net loss increased by approximately $5.2 million, or 230.0%, to $7.5 million for the three months ended September 30, 2012 from $2.3 million during the same period in 2011. The increase in net loss resulted primarily from an increase in financial expenses of approximately $4.1 million (see above for explanation), a decrease of approximately $0.9 million in gross profit (see above for explanation) and an increase of approximately $0.3 million in operating expenses (see above for explanation).

Six Month Period Ended June 30, 2012 Compared to Six Month Period Ended June 30, 2011

Revenue. For the six month period ended June 30, 2012, total revenue decreased approximately $0.6 million, or 24.0%, to approximately $2.1 million from approximately $2.7 million during the same period in 2011. The $0.6 million decrease was attributable to a decrease in sales volume, as described more fully below. The following is an explanation of the approximately $0.6 million decrease in revenue broken down by its main two components, a decrease in gross revenues of approximately $0.5 million and a net decrease in deferred revenues recognized of approximately $0.1 million.

For the six month period ended June 30, 2012, total gross revenue decreased by approximately $0.5 million, or 19.6%, to approximately $2.0 million from approximately $2.5 million during the same period in 2011. This decrease in total gross revenue is predominantly sales volume based, with decreased sales volume accounting for approximately $340,000, or approximately 13.0%, and price decreases to our repeat distributors accounting for the remaining approximately $150,000, or approximately 6.0%. With respect to

TABLE OF CONTENTS

individual markets, this decrease in gross revenue was mainly attributable to the fact that we did not have any sales to our distributor in India during the six month period ended June 30, 2012, compared to sales of approximately $1.2 million to this distributor during the same period in 2011, a decrease of approximately $0.2 million of gross revenue from our distributor in Spain, a decrease of approximately $0.1 million of gross revenue from our distributor in Argentina, a decrease of approximately $0.1 million of gross revenue from our distributor in France and a decrease of approximately $0.1 million of gross revenue from our distributor in Israel. These decreases were partially offset by an increase of approximately $0.5 million of gross revenues from our distributor in Russia, an increase of approximately $0.2 million of gross revenue from our distributor in Italy, an increase of approximately $0.2 million of gross revenue from our distributor in Germany, an increase of approximately $0.1 million of gross revenue from our distributor in Poland, and an increase of approximately $0.1 million of gross revenue from our distributor in Mexico, and an increase of approximately $0.1 million from our remaining distributors, all due to higher sales volumes to these distributors.

For the six month period ended June 30, 2012, net deferred revenue recognized decreased by approximately $0.1 million, or 66.8%, to approximately $0.1 million from approximately $0.2 million during the same period in 2011. This decrease was almost entirely sales volume based, partially offset by approximately $0.1 million in price increases to our repeat distributors. The deferred revenue recognized during the six month period ended June 30, 2012 was comprised primarily of approximately $0.1 million of revenue that we deferred from a shipment to India in the first six months of 2011. Our net deferred revenue for the six month period ended June 30, 2011 consisted of approximately $0.1 million of deferred revenue from our distributor in India, offset by recognized revenue of approximately $0.1 million from our distributors in Israel, approximately $0.1 million from our distributor in Brazil, and approximately $0.1 million from other distributors.

Gross Profit. For the six month period ended June 30, 2012, gross profit (revenue less cost of revenues) decreased 41.5%, or approximately $0.5 million, to approximately $0.7 million from approximately $1.2 million during the same period in 2011. Gross margin decreased from 43.5% in the six month period ended June 30, 2011 to 33.5% in the six month period ended June 30, 2012. In addition to our decrease in sales, the primary reason for the decrease in gross profit was a write-off of approximately $0.4 million of slow moving inventory, which accounted for approximately 89.7% of the decrease mentioned above. We were able to partially offset these decreases with reduced production cost per stent driven by economies of scale. For the six month period ended June 30, 2012, our average selling price per stent recognized in revenue was $584, and we recognized the sale of 3,548 stents, compared to an average price of $541 per stent and 5,040 stents recognized in revenue for the same period in 2011. Our cost of goods sold per stent increased from an average of $305 per stent recognized in revenue for the six month period ended June 30, 2011 to an average of $388 per stent for the same period in 2012.

Research and Development Expense. For the six month period ended June 30, 2012, research and development expense increased 138.5% or approximately $1.5 million, to approximately $2.6 million, from approximately $1.1 million during the same period in 2011. The increase in cost resulted primarily from higher clinical trial expenses of approximately $1.2 million, attributable mainly to the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately $0.7 million), the U.S. Food and Drug Administration clinical trial (approximately $0.3 million) and the MGuard Carotid clinical trial (approximately $0.2 million), an increase of approximately $0.1 million in salaries, approximately $0.1 million in share-based compensation and approximately $0.1 million in miscellaneous expenses. Research and development expense as a percentage of revenue increased to 125.9% for the six month period ended June 30, 2012 from 40.1% in the same period in 2011.

Selling and Marketing Expense. For the six month period ended June 30, 2012, selling and marketing expense increased 19.2%, or approximately $0.2 million, to approximately $1.2 million, from approximately $1.0 million during the same period in 2011. The increase in selling and marketing expense resulted primarily from approximately

$0.2 million of additional salaries and approximately $0.1 million of additional share-based compensation principally for newly hired sales personnel in connection with the expansion of our sales activities worldwide, and approximately $0.2 million in advertising expenses. This increase was partially offset by a decrease of approximately $0.1 million of commissions pertaining mainly to our first time shipment of approximately $1.2 million to our distributor in India during the six month period ended June 30, 2011 (no

TABLE OF CONTENTS

such sale occurred in the same period of 2012), approximately $0.1 million in share-based compensation to consultants and approximately $0.1 million in miscellaneous expenses. Selling and marketing expense as a percentage of revenue increased to 60.2% for the six month period ended June 30, 2012 from 38.3% in the same period in 2011.

General and Administrative Expense. For the six month period ended June 30, 2012, general and administrative expense increased 67.3%, or approximately $1.6 million, to approximately $4.0 million from $2.4 million during the same period in 2011. The increase resulted primarily from an increase in share-based compensation of $1.2 million, predominately related to directors compensation, an increase of approximately $0.2 million in rent expense related to our move to a new location to support our expanding sales activities, an increase of approximately $0.1 million in audit fees to accommodate and comply with the reporting requirements of the Securities and Exchange Commission, approximately $0.1 million in legal fees, related primarily to compliance with the reporting requirements of the Securities and Exchange Commission, approximately $0.1 million of fees paid to consultants that was also related primarily to compliance with the reporting requirements of the Securities and Exchange Commission, and approximately $0.3 million in miscellaneous expenses. This increase was partially offset by a decrease of approximately $0.4 million in litigation expenses. General and administrative expense as a percentage of revenue increased to 193.1% for the six month period ended June 30, 2012 from 87.7% in the same period in 2011.

Financial Expenses (Income). For the six month period ended June 30, 2012, financial expense decreased 113.9%, or approximately $0.9 million, to approximately $0.1 million of financial income from $0.8 million of financial expense during the same period in 2011. The decrease in expense resulted primarily from approximately $1.3 million of financial income from the revaluation of warrants pertaining to our convertible debentures, partially offset by approximately $1.2 million of amortization expense pertaining to the same convertible debentures and their related issuance costs in the six month period ended June 30, 2012, as compared to a one-time financial expense recording of approximately $0.6 million in the first six month period of 2011 pertaining to the revaluation of an outstanding convertible loan at fair value prior to redemption and approximately $0.2 million for the favorable impact of exchange rate differences for the six month period ended June 30, 2011. Financial expense as a percentage of revenue was 28.9% for the six month period ended June 30, 2011, compared to 5.3% of financial income for the same period in 2012.

Tax Expenses. Tax expense remained relatively flat at $32,000 for the six month period ended June 30, 2012, as compared to $20,000 during the same period in 2011.

Net Loss. Our net loss increased by approximately $2.9 million, or 70.7%, to $7.1 million for the six month period ended June 30, 2012, from $4.2 million during the same period in 2011. The increase in net loss resulted primarily from an increase in operating expenses of approximately $3.3 million (see above for explanation) and a decrease of approximately $0.5 million in gross profit (see above for explanation). This increase was partially offset by a decrease in financial expenses (income) of approximately $0.9 million (see above for explanation).

Twelve Months Ended December 31, 2011 Compared to Twelve Months Ended December 31, 2010

Revenue. For the twelve months ended December 31, 2011, total revenue increased approximately $1.1 million, or 21.3%, to approximately $6.0 million from approximately $4.9 million during the same period in 2010. The $1.1 million increase was attributable primarily to an increase in sales volume, as described more fully below. The following is an explanation of the approximately $1.1 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $2.5 million offset by a net decrease in deferred revenues of approximately $1.4 million.

For the twelve months ended December 31, 2011, total gross revenue increased by approximately $2.5 million, or 77.6%, to approximately $5.7 million from approximately $3.2 million during the same period in 2010. This increase in total gross revenue was predominantly sales volume based, with increased sales volume accounting for approximately $2.3 million, or approximately 72.5%, and price increases accounting for the remaining approximately $0.2 million, or approximately 5.1%. In general, we focused on opening new markets, such as India, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuard Coronary. With respect to individual markets, this increase in gross revenue is mainly attributable to the first time shipment of approximately

TABLE OF CONTENTS

$1.2 million to our distributor in India during the twelve months ended December 31, 2011, an increase of approximately $0.4 million of gross revenue from our new distributor in Russia, an increase of approximately $0.4 million of gross revenue from our distributor in Israel, an increase of approximately $0.3 million of gross revenue from our distributor in Brazil, an increase of approximately $0.2 million of gross revenue from our distributor in Spain, an increase of approximately $0.2 million of gross revenue from our distributor in Argentina, an increase of approximately $0.1 million of gross revenue from our distributor in South Africa, an increase of approximately $0.1 million of gross revenue from our new distributor in Ukraine, an increase of approximately $0.1 million of gross revenue from our new distributor in the Netherlands and an increase of approximately $0.1 million of gross revenue from our distributor in Mexico. This increase was partially offset by a decrease of approximately $0.2 million in gross revenue from our distributor in Germany, a decrease of approximately $0.2 million in gross revenue from our distributor in Pakistan, a decrease of approximately $0.2 million from our distributor in Poland, a decrease of approximately $0.1 million in gross revenue from our distributor in Italy, and a decrease of approximately $0.1 million in gross revenue to our distributor in France, all due to lower sales volume to these distributors. We also shipped and recognized gross revenue for approximately $0.2 million more from our remaining distributors during the twelve months ended December 31, 2011, as compared to the same period in 2010.

For the twelve months ended December 31, 2011, net deferred revenue recognized decreased by approximately $1.4 million, or 83.8%, to approximately $0.3 million from approximately $1.7 million during the same period in 2010. The key driver of this decrease was a decrease in the volume of revenue deferred to 2011 compared to the volume of revenue deferred to 2010, accounting for approximately $1.3 million or approximately 74.5%, with the remaining approximately $0.1 million, or 9.3%, being driven by price decreases in the revenue deferred to 2011 compared to the revenue deferred to 2010. Revenue recognition out of deferred income had less of an impact in 2011 as compared to 2010 due to the fact that we deferred mainly shipments in 2008 and 2009 that were recognized in 2010. In 2010, only a small set of customers had a large portion of their revenues deferred until 2011.

For the twelve months ended December 31, 2011, our net deferred revenue consisted of approximately $0.2 million attributable to our distributor in Israel, approximately $0.1 million to our distributor in Brazil, and approximately $0.1 million to our distributor in Poland, offset by approximately $0.1 million deferred for a shipment to our distributor in India. Our distributor in Israel had a contractual right to return all purchases to us within 18 months of the purchase date. Due to our inability to accurately estimate the amount of future returns, all sales to this distributor were deferred until this 18 month return period elapsed. On May 9, 2011, our distributor in Israel agreed to revoke its previous rights to return purchases, resulting in all future sales being final. The deferred revenue of approximately $0.2 million recognized during the twelve months period ended December 31, 2011 accounted for all previous purchases by the distributor that the distributor no longer had a contractual right to return and were not yet recognized as revenues. Our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. Due to our inability to accurately estimate the amount of future returns by our distributor in Brazil, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately $0.1 million recognized during the twelve months period ended December 31, 2011 accounted for purchases made in December 2010 that were not returned by the Brazilian distributor and were not yet recognized as revenues. In 2011, it was decided that due to lack of actual returns from the Brazilian distributor, despite the clause in its contract, we will no longer defer revenue pertaining to current shipments. Our distributor in India made its first purchase in 2011. Because of our inexperience with this distributor, management decided to defer a portion of the shipment to 2012, when it could better determine if a portion of it would be returned.

For the twelve months ended December 31, 2010, net deferred revenue recognized of approximately $1.7 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Poland of approximately $1.3 million, to our distributor in Brazil of approximately $0.3 million, and to our distributor in Sri Lanka of approximately $0.1 million. For the twelve months ended December 31, 2010, our distributor in Poland, subject to our sole discretion, had the

right to return our products. Because we were unable to develop estimates for the level of returns, the $1.3 million worth of shipments made to the distributor in Poland that we recorded as deferred revenues were only recognized during the twelve months ended December 31, 2010 as revenues. As noted above, our distributor in Brazil has a contractual right to return all purchases for up to

TABLE OF CONTENTS

six months from the delivery date. As also noted above, due to our inability to accurately estimate the rate of return by this distributor, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately $0.3 million recognized during the twelve months period ended December 31, 2010 accounted for purchases made in December 2009 that were not returned and were not yet recognized as revenues.

Gross Profit. For the twelve months ended December 31, 2011, gross profit increased 32.8%, or approximately $0.7 million, to approximately $3.0 million from approximately $2.3 million during the same period in 2010. Gross margin increased from 45.5% in the twelve months ended December 31, 2010 to 49.9% in the twelve months ended December 31, 2011. In addition to an increase in sales, we were able to improve our gross profit because of reduced production cost per stent driven by reduction in price per unit from our subcontractor and economies of scale. For the twelve months ended December 31, 2011, our average selling price per stent recognized in revenue was $571, and we recognized the sale of 10,523 stents, compared to an average price of $606 per stent and 8,171 stents recognized in revenue for the same period in 2010. Our cost of goods sold per stent decreased from an average of $330 per stent recognized in revenue for the twelve months ended December 31, 2010 to an average of $286 per stent for the same period in 2011. The higher price per stent for the twelve months ended December 31, 2010 was effected by the price of stents sold in 2008 and 2009 to one of our European distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of $997 when translated to U.S. dollars.

Research and Development Expense. For the twelve months ended December 31, 2011, research and development expense increased 84.9%, or approximately $1.2 million, to approximately $2.5 million from approximately $1.3 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately $1.2 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately $0.9 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately $0.3 million), and an increase of approximately $0.3 million in salaries, offset by an approximately $0.2 million reduction in miscellaneous expenses and an approximately $0.1 million reduction in share-based compensation. Research and development expense as a percentage of revenue increased to 41.2% for the twelve months ended December 31, 2011 from 27.0% in the same period of 2010.

Selling and Marketing Expense. For the twelve months ended December 31, 2011, selling and marketing expense increased 59.6%, or approximately $0.7 million, to approximately $2.0 million, from approximately $1.3 million during the same period in 2010. The increase in selling and marketing expense resulted primarily from approximately $0.3 million of additional salaries and approximately $0.4 of share-based compensation principally for newly hired sales personnel in connection with the expansion of our sales activities worldwide, and approximately $0.1 million of commissions pertaining mainly to our first time shipment of approximately $1.2 million to our distributor in India. This increase was partially offset by a decrease of approximately $0.1 million in advertising expenses. Selling and marketing expense as a percentage of revenue increased to 32.9% in 2011 from 25.0% in 2010.

General and Administrative Expense. For the twelve months ended December 31, 2011, general and administrative expense increased 323.6%, or approximately $9.4 million, to approximately $12.3 million from $2.9 million during the same period in 2010. The increase resulted primarily from an increase in share-based compensation of $7.5 million, which predominately pertains to directors compensation, an increase of approximately $0.5 million in salary expenses (due to an increase in employee infrastructure to accommodate and comply with the reporting requirements of the Securities and Exchange Commission), an increase in investor related activities of approximately $0.5 million (due to us having been a publicly reporting company during the twelve months ended December 31, 2011, but not during the same period in 2010), an increase of approximately $0.5 million in litigation expenses (primarily due to a provision for our potential loss related to a threatened lawsuit from a finder claiming a future success fee and commissions for assistance in finding our distributor in Brazil), approximately $0.3 million in legal fees (also related primarily to compliance with the reporting requirements of the Securities and Exchange Commission), and

approximately $0.2 million in audit fees to accommodate and comply with the reporting requirements of the Securities and Exchange

TABLE OF CONTENTS

Commission. This increase was partially offset by a decrease of approximately $0.1 million in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 204.4% in 2011 from 58.6% in 2010.

Financial Expenses (Income). For the twelve months ended December 31, 2011, financial expense increased 506.5%, or approximately $0.8 million, to approximately $1.0 million from $0.2 million during the same period in 2010. The increase in expense resulted primarily from a one-time financial expense recording of approximately $0.6 million in the first quarter of 2011 pertaining to the revaluation of an outstanding convertible loan at fair value prior to redemption and approximately $0.2 million for the favorable impact of exchange rate differences for the twelve months ended December 31, 2010 that did not occur during the twelve months ended December 31, 2011. Financial expense as a percentage of revenue increased from 3.1% in 2010, to 15.6% in 2011.

Tax Expenses. Tax expense remained relatively flat at $2,000 for the twelve months ended December 31, 2011, as compared to $47,000 during the same period in 2010.

Net Loss. Our net loss increased by approximately $11.3 million, or 328.8%, to $14.7 million for the twelve months ended December 31, 2011 from $3.4 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately $11.2 million (see above for explanation) and an increase of approximately $0.8 million in financial expenses (income) (see above for explanation). This increase was partially offset by an increase in gross profit of approximately $0.7 million (see above for explanation).

Twelve Months Ended December 31, 2010 Compared to Twelve Months Ended December 31, 2009

Revenues. For the twelve months ended December 31, 2010, total revenue increased approximately $1.5 million, or 45.1%, to approximately $4.9 million from approximately $3.4 million in 2009. The $1.5 million increase in revenue was primarily attributable to an increase in the amount of net deferred revenues recognized during 2010.

For a description of the revenue deferred to 2010, see Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010 above.

For the twelve months ended December 31, 2009, net deferred revenue of approximately $0.1 million was comprised mainly of shipments made in 2009 but deferred and recognized in 2010 to our distributor in Brazil in the amount of approximately $0.4 million, to our distributor in Poland in the amount of $0.2 million and to our distributor in Israel in the amount of $0.2 million, offset by shipments made in 2008 but deferred and recognized in revenue in 2009 from our distributor in Italy in the amount of $0.5 million, and from our distributor in Cyprus in the amount of $0.2 million. Because 2008 was our first year of sales and we were unable to accurately estimate the amount of future returns of our products, all revenues from shipments made in 2008 were deferred and recognized in 2009. The deferred revenue for each distributor recognized during the twelve month period ended December 31, 2009 accounted for the purchases made in the twelve month period ended December 31, 2008 that were not returned by either distributor and were not yet recognized as revenues. See also Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010 above for the reasons why such revenue was deferred and/or recognized for certain of the distributors listed above.

Total gross revenue for the twelve months ended December 31, 2010 remained relatively flat in comparison to the twelve months ended December 31, 2009, increasing by approximately $46,000. This increase was predominantly sales volume based, with increased sales volume accounting for approximately $263,000, offset by price decreases in

the amount of $217,000. The increase in sales volume was evenly distributed among our distributors. The decrease in prices were due to our penetration of newly opened markets, namely Brazil, Slovakia and Cyprus in 2010, which required reduced prices as compared to 2009.

Gross Profit. For the twelve months ended December 31, 2010, gross profit (revenue less cost of revenues) increased 101.2%, or approximately $1.1 million, to approximately $2.2 million from approximately $1.1 million during the same period in 2010. Our gross margin percentage for the twelve months ended December 31, 2010 increased to 45.5% of revenues, compared to 32.8% during the same period in 2009. In addition to an increase in sales, we were able to improve our gross profit because of reduced production cost

TABLE OF CONTENTS

per stent driven by reduction in price per unit from our subcontractor and economies of scale. For the twelve months ended December 31, 2010, our average selling price per stent recognized in revenue was $606, and we recognized the sale of 8,171 stents, compared to an average price of $577 per stent and 5,910 stents recognized in revenue for the same period in 2009. Our cost of goods sold per stent decreased from an average of $380 per stent recognized in revenue for the twelve months ended December 31, 2009 to an average of $330 per stent for the same period in 2010. The higher price per stent for the twelve months ended December 31, 2010 was affected by the price of stents sold in 2008 and 2009 to one of our Europeans distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of $997 when translated to U.S. dollars.

Research and Development Expense. For the twelve months ended December 31, 2010, research and development expense remained relatively flat at approximately $1.3 million as compared to the same period in 2009. Research and development expense as a percentage of revenue decreased to 27.0% in 2010 from 39.0% in 2009.

Selling and Marketing Expense. For the twelve months ended December 31, 2010, selling and marketing expense increased by approximately $0.2 million, or 18.8%, to approximately $1.2 million from approximately $1.0 million during the same period in 2009. The increase in cost resulted primarily from an increase of approximately $0.2 million in advertising expenses. Selling and marketing expense as a percentage of revenue decreased to 25.0% in 2010 from 30.5% in 2009.

General and Administrative Expense. For the twelve months ended December 31, 2010, general and administrative expense increased approximately $1.4 million, or 97.5%, to approximately $2.9 million from approximately $1.5 million during the same period in 2009. The increase resulted primarily from an increase in share-based compensation of approximately $0.7 million (of which approximately $0.5 million related to employees and $0.2 million related to directors), an increase of approximately $0.2 million in audit fees (as we prepared for the transition from generally accepted accounting principles in Israel to the United States), an increase of $0.1 million in salary expenses, and an increase of approximately $0.4 million in other expenses (due to our overall expansion). General and administrative expense as a percentage of revenue increased to 58.6% in 2010 from 43.0% in 2009.

Financial Expenses (Income). For the twelve months ended December 31, 2010, financial expense increased to approximately $0.2 million from income of $4,000 for the same period in 2009. The increase in expense resulted primarily from a one-time financial income recording of $0.3 million in 2009 pertaining to the cancellation of the conversion feature of a convertible loan that was repaid in the same year. Financial expense as a percentage of revenue increased to 3.1% in 2010, compared to financial income as a percent of revenue of 1.2% in 2009.

Tax Expenses. Tax expense remained flat at $47,000 for the twelve months ended December 31, 2010 and 2009. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by approximately $0.7 million, or 25.6%, to approximately $3.4 million in 2010 from approximately $2.7 million during the same period in 2009. The increase in net loss resulted primarily from an increase in operating expenses of approximately $1.6 million (see above for explanation) and an increase of approximately $0.2 million in financial expenses (see above for explanation). This increase was partially offset by an increase in gross profit of approximately $1.1 million (see above for explanation).

Liquidity and Capital Resources

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

Since our formation, we have had recurring losses and negative cash flows from operating activities and have significant future commitments. For the three months ended September 30, 2012, we had losses of approximately $7.5 million and negative cash flows from operating activities of approximately $2.4 million. Additionally, as of September 30, 2012, we had a capital deficiency of $756,000. We believe that our working capital as of September 30, 2012 of approximately $8.6 million should enable us to continue funding the negative cash flows from operating activities until October 2013, when our convertible debentures are subject to a non-contingent redemption option that could require us to make a payment of approximately $13.3

TABLE OF CONTENTS

million, including accrued interest. Since we expect to continue incurring negative cash flows from operations and in light of the potential cash requirement in connection with our convertible debentures, there is substantial doubt about our ability to continue operating as a going concern.

Based on our financial position as of September 30, 2012, we will need to raise further capital at some future point in time, through the sale of additional equity securities or debt. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our MGuard products, our development of future products and competing technological and market developments. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. In addition, the terms of any securities we issue in future financings 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. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing or halting our U.S. Food and Drug Administration clinical trials or entering into financing agreements with unattractive terms.

General. At September 30, 2012, we had cash and cash equivalents of approximately $8.3 million, as compared to $10.3 million as of June 30, 2012. The decrease is attributable primarily to our net loss, excluding non-cash financial expenses. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately $2.4 million for the three months ended September 30, 2012 and $2.1 million for the same period in 2011. The principal reasons for the usage of cash in our operating activities for the three months ended September 30, 2012 include a net loss of approximately $7.5 million, offset by approximately $4.0 million in non-cash financial expenses, approximately $1.0 million in non-cash share-based compensation and a decrease in working capital of approximately $0.1 million.

Cash used in our investing activities was approximately $57,000 during the three months ended September 30, 2012, compared to approximately $264,000 of cash generated by investing activities during the same period in 2011. The principal reason for the decrease in cash flow from investing activities during 2012 was the purchase of approximately $35,000 of new manufacturing equipment and the funding of employee retirement funds of approximately $22,000.

Cash generated by financing activities was approximately $0.4 million for the three months ended September 30, 2012, compared to $1.4 million generated from financing activities for the same period in 2011. The principal source of cash from financing activities during the three months ended September 30, 2012 was funds received for the exercise of options and warrants in the amount of approximately $0.4 million. In contrast, during the three months ended September 30, 2011, we received approximately $1.5 million from the exercise of options, partially offset by a repayment of a long term loan of approximately $0.1 million.

As of September 30, 2012, our current assets exceeded current liabilities by a multiple of 3.6. Current assets decreased approximately $2.3 million during the three month period, mainly due to cash used in operations, and current liabilities decreased by approximately $0.2 million during the same period. As a result, our working capital surplus decreased by approximately $2.1 million to approximately $8.6 million during the three months ended September 30, 2012.

Six Month Period Ended June 30, 2012 Compared to the Six Month Period Ended June 30, 2011

General. At June 30, 2012, we had cash and cash equivalents of approximately $10.3 million, as compared to $8.0 million at June 30, 2011. The increase is attributable primarily to the issuance of senior secured convertible debentures and warrants on April 5, 2012.

Cash used in our operating activities was approximately $4.4 million for the six month period ended June 30, 2012, and approximately $1.8 million for the same period in 2011. The principal reasons for the usage of cash in our operating activities for the six month period ended June 30, 2012 included a net loss of approximately $7.1 million and approximately $1.3 million in non-cash financial income related to the

TABLE OF CONTENTS

revaluation of warrants pertaining to our convertible debentures, offset by approximately $1.9 million in non-cash share-based compensation, approximately $1.0 million in non-cash financial expense related to our convertible debentures, a decrease in working capital of approximately $0.9 million (driven primarily from a decrease in our accounts receivable of approximately $0.5 million due to our decrease in sales and an increase of approximately $0.5 million in other payables due to accruals recorded pertaining to the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) and the U.S. Food and Drug Administration clinical trial) and approximately $0.2 million of all other adjustments.

Cash used by our investing activities was approximately $0.2 million during the six month period ended June 30, 2012, compared to approximately $0.1 million during the same period in 2011. The principal reason for the increase in cash used in investing activities during 2012 was the purchase of approximately $0.2 million of new equipment.

Cash flow generated from financing activities was approximately $9.8 million for the six month period ended June 30, 2012, and $9.4 million for the same period in 2011. The principal source of cash flow from financing activities during 2012 was the proceeds from our convertible debentures and warrants issued on April 5, 2012 of approximately $9.9 million, offset by the repayment of a long-term loan in the amount of approximately $0.1 million. The principal source of cash flow from financing activities during the six month period ended June 30, 2011 was the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances prior to and after the share exchange transactions in the aggregate amount of approximately $10.6 million, offset by the repayment of a convertible loan in the amount of approximately $1.0 million and the partial repayment of a long-term loan in the amount of approximately $0.2 million.

As of June 30, 2012, our current assets exceeded current liabilities by a multiple of 4.1. Current assets increased approximately $4.5 million during the six month period ended June 30, 2012, mainly due to cash raised from the convertible debenture and warrant offering on April 5, 2012, and current liabilities increased by approximately $0.1 million during the same period. As a result, our working capital surplus increased by approximately $4.4 million to approximately $10.8 million during the six month period ended June 30, 2012.

Long-Term Loan. Prior to June 30, 2012, we had a long-term loan in the amount of approximately $0.1 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. The loan was payable in eight quarterly installments during a period of three years that began in April 2010. According to the loan agreement, in case of an exit transaction (defined as certain merger or sale transactions, or an initial public offering), we were required to pay to the bank an additional $0.25 million if the sum received in the transaction was higher than $100.0 million. The loan was repaid in January 2012.

Sales of Stock/Issuance of Debt and Securities. For the six month period ended June 30, 2012, we issued senior secured convertible debentures due April 5, 2014 in the original aggregate principal amount of $11,702,128 and five-year warrants to purchase an aggregate of 835,866 shares of our common stock at an exercise price of $7.20 per share (as adjusted for the anticipated one-for-four reverse stock split of our common stock) in exchange for aggregate gross proceeds of $11.0 million, with corresponding net proceeds of approximately $9.9 million. The convertible debentures were issued with a 6% original issuance discount, bear interest at an annual rate of 8% and are convertible at any time into shares of common stock at an initial conversion price of $7.00 per share (as adjusted for the anticipated one-for-four reverse stock split of our common stock). Upon conversion of the convertible debentures, investors will receive a conversion premium equal to 8% per annum, with a limit of 12% for the term of the convertible debentures, of the principal amount being converted. In addition, the investors may require us to redeem the convertible debentures at any time after October 5, 2013 (18 months after the date of issuance) for 112% of the then outstanding principal amount, plus all accrued interest, and we may prepay the convertible debentures after six months for 112% of the then outstanding principal amount, plus all accrued interest. In connection with this financing,

we paid placement agent fees of $848,750 and issued placement agents warrants to purchase 78,078 shares of common stock (as adjusted for the anticipated one-for-four reverse stock split of our common stock), with terms identical to the warrants issued to the investors.

TABLE OF CONTENTS

Twelve Months Ended December 31, 2011 Compared to Twelve Months Ended December 31, 2010

General. At December 31, 2011, we had cash and cash equivalents of approximately $5.1 million, as compared to $0.6 million at December 31, 2010. The increase was primarily attributable to the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances prior to and after the share exchange transactions.

Cash used in our operating activities was approximately $6.0 million for the twelve months ended December 31, 2011, and approximately $2.7 million for the same period in 2010. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2011 included a net loss of approximately $14.7 million and a decrease in working capital of approximately $2.0 million, offset by approximately $9.6 million in non-cash share-based compensation, an approximately $0.9 million in non-cash financial expenses related to the revaluation of a convertible loan and approximately $0.2 million of all other adjustments.

Cash provided by our investing activities was approximately $13,000 during the twelve months ended December 31, 2011, compared to approximately $46,000 of cash used by investing activities during the same period in 2010. The principal reason for the decrease in cash flow from investing activities during 2011 was a decrease in restricted cash of approximately $160,000, offset by the purchase of approximately $140,000 of new manufacturing equipment.

Cash flow generated from financing activities was approximately $10.7 million for the twelve months ended December 31, 2011, and $3.0 million for the same period in 2010. The principal reason for the increase in cash flow from financing activities during 2011 was the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances and exercise of options prior to and after the share exchange transactions in the aggregate amount of approximately $12.1 million, offset by the repayment of a convertible loan in the amount of approximately $1.0 million and the partial repayment of a long-term loan in the amount of approximately $0.4 million.

As of December 31, 2011, our current assets exceeded current liabilities by a multiple of 2.8. Current assets increased approximately $5.9 million during 2011, mainly due to cash raised from the private placements in 2011, while current liabilities decreased approximately $0.5 million during the same period. As a result, our working capital surplus increased by approximately $6.4 million to approximately $6.3 million during the twelve months ended December 31, 2011.

Long-Term Loan. As of December 31, 2011, we had a long-term loan outstanding in the amount of approximately $0.1 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. See Six month period ended June 30, 2012 compared to six month period ended June 30, 2011 Long-Term Loan.

Convertible Loans. Prior to December 31, 2011, we had convertible loans outstanding with an aggregate principal amount outstanding of approximately $1.58 million that bore interest at the rate of 8% per annum. Following the share exchange transactions on March 31, 2011, $580,000 plus accrued interest converted into shares of our common stock and warrants to purchase shares of our common stock. The remaining principal in the amount of $1.0 million, plus all accrued interest, was repaid on May 15, 2011.

Sales of Stock. For the twelve months ended December 31, 2011, we issued an aggregate of 3,078,786 shares of common stock and warrants to purchase 1,677,268 shares of common stock (each, as adjusted for the anticipated one-for-four reverse stock split of our common stock) for gross proceeds of approximately $13.7 million and

corresponding net proceeds of approximately $12.1 million.

Twelve Months Ended December 31, 2010 Compared to Twelve Months Ended December 31, 2009

General. At December 31, 2010, we had cash and cash equivalents of approximately $0.6 million, as compared to $0.4 million at December 31, 2009.

Cash used in our operating activities was approximately $2.7 million for the twelve months ended December 31, 2010, and approximately $1.5 million for the same period in 2009. The principal reasons for the increase in cash used in operations in 2010 included a net loss of approximately $3.4 million, a decrease

TABLE OF CONTENTS

of approximately $1.6 million in deferred revenues offset by approximately $1.6 million of non-cash share-based compensation expense, an increase of approximately $0.4 million in other working capital and $0.3 million of other non-cash adjustments.

Cash used in investing activities was approximately $46,000 for the twelve months ended December 31, 2010 and approximately $0.3 million for the same period in 2009. The principal reasons for the decrease in cash flow from investing activities included approximately $81,000 for plant and equipment purchases offset by a decrease of approximately $52,000 in restricted cash.

Cash flow generated from financing activities was approximately $3.0 million for the twelve months ended December 31, 2010, and approximately $0.7 million for the same period in 2009. The principal reasons for the increase in cash flow from financing activities during 2010 were the issuance of approximately $1.8 million in new shares and the issuance of convertible loans of approximately $1.5 million, offset by the repayment of a long-term loan in the amount of approximately $0.3 million.

As of December 31, 2010, current assets were approximately equal with our current liabilities. Current assets decreased approximately $0.2 million during the twelve months ended December 31, 2010 while current liabilities decreased by approximately $1.5 million during the same period. As a result, our working capital deficiency decreased by approximately $1.2 million to approximately $53,000 during the twelve months ended December 31, 2010.

Newly Adopted Accounting Guidance

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04). ASU 2011-04 changes certain fair value measurement principles and clarifies the application of existing fair value measurement guidance. These amendments include, among others, (1) the application of the highest and best use and valuation premise concepts, (2) measuring the fair value of an instrument classified in a reporting entity s shareholders equity and (3) disclosing quantitative information about the unobservable inputs used within the Level 3 hierarchy. Effective January 1, 2012, we adopted ASU 2011-04. The adoption of this accounting standards update did not have a material impact on our consolidated financial statements.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

TABLE OF CONTENTS

Tabular Disclosure of Contractual Obligations

The following table summarizes our outstanding contractual obligations as of June 30, 2012:

	Payments Due By Period (in thousands)				
Contractual Obligations	Total	Less than 1 year	1 3 years	3 5 years	More than 5 years
Convertible loan[1]	$ 14,745	$ 703	$ 14,043	0	0
Operating lease obligations[2]	$ 913	$ 403	$ 510	0	0
Accounts Payable	$ 1,983	$ 1,983	$ 0	0	0
Total	$ 17,641	$ 3,089	$ 14,553	$	$

(1) Our convertible loan obligations as of June 30, 2012 consisted of senior secured convertible debentures issued to certain investors on April 5, 2012 in the aggregate amount of $11.7 million. Our convertible debentures bear interest at the rate of 8% per annum and are convertible at any time into shares of common stock at an initial conversion price of $7.00 per share (as adjusted for the anticipated one-for-four reverse stock split of our common stock). The holders of our convertible debentures may require us to redeem our convertible debentures at any point 18 months after the date of issuance for 112% of the outstanding principal amount.

(2) Our operating lease obligations consist of the lease for our offices and manufacturing facilities in Tel Aviv, Israel and the leases for the majority of our company cars.

TABLE OF CONTENTS

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest Rate Exposure

Our exposure to market risk relates primarily to short-term investments, including funds classified as cash equivalents. As of September 30, 2012, all excess funds were invested in time deposits and other highly liquid investments, therefore our interest rate exposure is not considered to be material.

Foreign Currency Exchange Rate Exposure

Our foreign currency exchange rate exposure continues to evolve as we grow internationally. Our exposure to foreign currency transaction gains and losses is the result of certain revenues and expenses being denominated in currencies other than the U.S. dollar, primarily the Euro and the New Israeli Shekel. We do not currently engage in hedging or similar transactions to reduce these risks. Fluctuations in currency exchange rates could impact our results of operations, financial position, and cash flows.

TABLE OF CONTENTS

BUSINESS

History

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.

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 12,666,666 shares of common stock (as adjusted for the anticipated one-for-four reverse stock split of our common stock) in exchange for all of InspireMD Ltd. s issued and outstanding ordinary shares, resulting in the former shareholders of InspireMD Ltd. holding a controlling interest in us and InspireMD Ltd. becoming our wholly-owned subsidiary. In addition, all options, warrants or other securities convertible into or exercisable for ordinary shares of InspireMD Ltd. were exchanged for options, warrants or other securities convertible into or exercisable for shares of our common stock.

Immediately following the share exchange transactions, we transferred all of our pre-share exchange operating assets and liabilities to our wholly-owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation, and transferred all of Saguaro Holdings, Inc. s outstanding capital stock to Lynn Briggs, our then-majority stockholder and our former president, chief executive officer, chief financial officer, secretary-treasurer and sole director, in exchange for the cancellation of 1,875,000 shares of our common stock (as adjusted for the anticipated one-for-four reverse stock split of our common stock) held by Ms. Briggs.

After the share exchange transactions and the divestiture of our pre-share exchange operating assets and liabilities, we succeeded to the business of InspireMD Ltd. as our sole line of business, and all of our then-current officers and directors resigned and were replaced by some of the officers and directors of InspireMD Ltd.

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.

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 micronet mesh sleeve over a stent (see photograph below of an MGuard stent). 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, with the aim of ensuring adequate protection from distal embolization (the dislodgement of particles from the artery wall that results in blood clot), 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. For the three months ended September 30, 2012, our total revenue was approximately $0.5 million and our net loss was approximately $7.5 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.

TABLE OF CONTENTS

MGuard Sleeve Microscopic View

We intend to study our MGuard technology for use in a broad range of coronary related situations in which complex lesions occur and intend to seek to make it an industry standard for treatment of acute coronary syndromes. We believe that patients will benefit from a cost-effective alternative which we believe will prove to have a superior clinical efficacy and safety profile than other stent technologies. We believe that with our MGuard technology, we are well positioned to emerge as a key player in the global stent market.

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.

Our initial MGuard Coronary product incorporated a stainless steel stent. We replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as the MGuard Prime version of the MGuard Coronary product. 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. In particular, according to Jabara, et al. (A Third Generation Ultra-thin Strut Cobalt Chromium Stent: Histopathological Evaluation in Porcine Coronary Arteries, EuroIntervention, November 2009), due to its greater density, cobalt-chromium enables the construction of stents that have both thinner struts and similar radial strength as stainless steel, with its thicker struts. In turn, Jabara, et al. found that the reduced thickness of the struts provides more flexibility and lower crossing profiles, thereby reducing the inflammatory response and neointimal thickening, potentially lowering restenosis and target vessel revascularization rates.

The MGuard Prime version of the MGuard Coronary product 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 help market our new cobalt-chromium based MGuard Prime version of the MGuard Coronary product.

However, we face a number of challenges to the further growth of our MGuard Coronary and other planned MGuard products. For example, 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. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. In addition, none of our products is currently approved by the U.S. Food and Drug Administration. Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard products 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. Furthermore, our rights to our intellectual property with respect to our products could be challenged, our ownership of such intellectual property rights could be challenged, or

MGuard Sleeve Microscopic View

TABLE OF CONTENTS

our products could be challenged in view of third party intellectual property rights. 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 products based on one or more of these patents. Additionally, there is a strong preference to use drug-eluting stents in some countries. Over the last decade, there has been an increasing tendency to use drug-eluting stents in percutaneous coronary intervention (PCI), commonly known as angioplasty (a therapeutic procedure to treat narrowed coronary arteries of the heart found in patients with heart disease), with a usage rate of drug-eluting stents in PCI approaching 70-80% in some countries, even though drug-eluting stents do not address thrombus management in acute myocardial infarction. Also, the use of other bare-metal stents is preferred over the use of MGuard products in certain circumstances, such as when placing the stent at the entrance to large side branches, known as jailing large side branches.

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.

Business Segment and Geographic Areas

For financial information about our one operating and reportable segment and geographic areas, refer to Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 13. Entity Wide Disclosures to our consolidated financial statements included elsewhere in this prospectus.

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 2011 MEDTECH OUTLOOK produced on January 3, 2011 by BMO Capital Markets, after registering a compounded annual growth rate from 2002 to 2009 of approximately 13%, revenues from the global coronary stent market is predicted to remain relatively constant, 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 2011 MEDTECH OUTLOOK produced on January 3, 2011 by the BMO Capital Markets, the percutaneous coronary intervention procedures involving stents are increasingly being used to treat coronary artery diseases with an 88.3% penetration rate in 2009.

Our Products

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

TABLE OF CONTENTS

MGuard Deployed in Artery

The protective sleeve is designed to provide several clinical benefits:

the mesh diffuses the pressure and the impact of deployment exerted by the stent on the arterial wall and reduces the injury to the vessel;
the protective sleeve reduces plaque dislodgement and blocks debris from entering the bloodstream during and post procedure (called embolic showers);
in future products, when drug coated, the mesh is expected to deliver better coverage and uniform drug distribution on the arterial wall and therefore potentially reduce the dosage of the active ingredient when compared to approved drug-eluting stents on the market; and
the protective sleeve maintains the standards of a conventional stent and therefore should require little to no additional training by physicians.

MGuard 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 and 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), indicate positive outcomes and safety measures. The results of these clinical trials for the MGuard Coronary stent suggest higher levels of reperfusion, lower rates of 30 day and 1 year major adverse cardiac events, and high levels of complete ST resolution, as compared to the levels and rates of other bare-metal and drug-eluting stents. MGuard Coronary demonstrated high levels of complete ST resolution (occurrence in 61% of patients in the MAGICAL study and 90% of patients in the PISCIONE study for the MGuard Coronary stent) and lower rates of 30 day and 1 year major adverse cardiac events (2.4% and 5.9%, respectively, for the MGuard Coronary stent), as compared to the levels and rates of other bare-metal and drug-eluting stents, as reported by Vlaar et. al. (Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study, Lancet 2008; 371: 1915 20). As reported in the study by Vlaar et. al., complete ST resolution occurred in 44.2% of patients with a bare-metal stent and 56.6% of patients with a bare-metal stent preceded by an aspiration procedure, and the 30 day and 1 year major adverse cardiac event rates were 9.4% and 20.3%, respectively, for patients with a bare-metal stent and 6.8% and 16.6%, respectively, for patients with a bare-metal stent preceded by an aspiration procedure. Furthermore, results from a recent HORIZONS-AMI trial demonstrated that 1 year major adverse cardiac event rates were 10.5% for patients with drug eluting stents. Complete ST resolution is the evidence of a quick and adequate disappearance of the pathologic ST elevation in the patient s electrocardiogram, which is the clear marker of STEMI. The faster and more complete the resolution is, the better recovery of the myocardium and the better prognosis for the patient. Vlaar et. al. reported that a higher complete ST resolution correlates with lower mortality and/or reinfarction rates among affected patients (cardiac mortality was

1.4% for patients with complete ST resolution compared to 15.3% for patients with no ST resolution).

TABLE OF CONTENTS

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 reperfusion levels and 30-day and 1-year major adverse cardiac event rates 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 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 ongoing 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. 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 in high risk patient populations. We intend that the embolic protection will result from the mesh sleeve, as it traps emboli at their source. In addition, we believe that 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. 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).

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

TABLE OF CONTENTS

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 plus 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	CQ4-2015	2016
MGuard Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	CQ1-2011	CQ1-2013	To be determined	To be determined	To be determined
MGuard Carotid Plus Bio-Stable Mesh	Carotid Arteries	CQ1-2011	CQ1-2013	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, we have determined that the expected commencement of sales in the European Union cannot be accurately predicted since we have delayed the development of this product until additional funding for its 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.

Pre-Clinical Studies

We performed laboratory and animal testing prior to submitting an application for CE Mark approval for our MGuard Coronary with bio-stable mesh. We also performed all CE Mark-required mechanical testing of the stent. We conducted pre-clinical animal trials at the CBSET lab in July 2006 and August 2007. In these animal trials, on average, the performance of the MGuard Coronary with bio-stable mesh was comparable with the performance of control bare-metal stents. Analysis also indicated that in these animal trials, the mesh produced levels of inflammation comparable with those levels produced by standard bare-metal stents. No human trials were conducted as part of these pre-clinical trials.

TABLE OF CONTENTS

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

Product	Stent Platform	Approval Requirement	Start of Study	End of Study
MGuard Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	CE Mark (European Union + Rest of World)	CQ4-2006	CQ3-2007
	Drug-Eluting Mesh (Bare-Metal Stent Plus Drug-Eluting Mesh)	CE Mark (European Union + Rest of World)	To be determined	To be determined
		FDA (U.S.)	To be determined	To be determined
	Cobalt-Chromium Stent Plus Bio-Stable Mesh	FDA (U.S.)	CQ2-2011	CQ2-2012
MGuard Peripheral/Carotid	Self-Expanding System Plus Mesh	CE Mark (European Union + Rest of World)	CQ3 2012	CQ1 2013

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

With respect to the preclinical studies for MGuard Peripheral/Carotid, the start of study of the Self Expending System Plus Mesh trial has been delayed from our previously announced target due to a delay in our receipt of anticipated funding.

Clinical Trials

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

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	Study Status			
					No. of Patients	Start Enrollment	End Enrollment	End of Study
MGuard Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	two Germany sites	12 months	Study to evaluate safety and performance of MGuard	41	CQ4-2006	CQ4-2007	CQ2-2008

		system				
Brazil one site	12 months		30	CQ4-2007	CQ1-2008	CQ2-2009
Poland four sites	3 years		60	CQ2-2008	CQ3-2008	CQ2-2009
International MGuard Observational Study worldwide 50 sites	12 months		Up to 1,000	CQ1-2008	CQ4-2013	CQ4-2013
Israeli MGuard Observational Study Israel 8 sites	6 months		Up to 100	CQ2-2008	CQ3-2011	CQ3-2012

TABLE OF CONTENTS

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	Study Status No. of Patients	Start Enrollment	End Enrollment	End of Study
		Master randomized control trial 9 countries, 50 centers in South America, Europe and Israel	12 months		433	CQ2-2011	CQ2-2012	CQ2-2013
		Brazil Observational Study 25 sites	12 months		Up to 500	CQ3-2010	To be determined	To be determined
		FDA Study 70 sites, U.S. and out of U.S.	12 months	Pilot study to evaluate safety and performance of MGuard system for FDA approval	1,100	CQ1-2013	CQ2-2014	CQ3-2015
	Drug-Eluting Stent (Bare-Metal Stent + Drug Eluting Mesh)	South America and Europe 10 sites	12 months	Pilot study to evaluate safety and performance of MGuard system for FDA and CE Mark approval	500	To be determined	To be determined	To be determined
		U.S. 50 sites	12 months		2,000	To be determined	To be determined	To be determined
		Rest of World as an Observational Study	12 months to 3 years	Evaluation of safety and efficacy for specific indications	400	To be determined	To be determined	To be determined
MGuard Peripheral	Self-Expanding System + Mesh	South America and Europe four sites	12 months	Pilot study to evaluate safety and performance of MGuard system for CE Mark approval	50	To be determined	To be determined	To be determined
MGuard Carotid	Self-Expanding System +	Rest of World as a registry	9 months	Evaluation of safety and	150	To be determined	To be determined	To be determined

Mesh	study	efficacy for specific indications post-marketing

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

The MGuard Coronary clinical trials for the drug-eluting stent have been delayed from our previously announced target due to a delay in our receipt of anticipated funding.

With respect to the MGuard Peripheral clinical trial for the self-expanding system plus mesh, the start date has been delayed from our previously announced start date due to a delay in our receipt of anticipated funding.

With respect to the MGuard Carotid clinical trial for the self-expanding system plus mesh, the number of patients has been decreased due to feedback from the clinical trial leaders that a smaller patient population would be sufficient for this clinical trial.

Completed Clinical Trials for MGuard Coronary Bare-Metal Stent Plus Bio-Stable Mesh

As shown in the table above, we have completed three clinical trials with respect to our MGuard Coronary with bio-stable mesh. Our first study, conducted at two centers in Germany, included 41 patients

TABLE OF CONTENTS

with either saphenous vein graft coronary interventions or native coronary lesions treatable by a stenting procedure (blockages where no bypass procedure was performed). The MGuard Coronary rate of device success, meaning the stent was successfully deployed in the target lesion, was 100% and the rate of procedural success, meaning there were no major adverse cardiac events prior to hospital discharge, was 95.1%. At six months, only one patient (2.4% of participants) had major Q-wave myocardial infarction (QWMI) and 19.5% of participants had target vessel revascularization (an invasive procedure required due to a stenosis in the same vessel treated in the study). This data supports MGuard Coronary s safety in the treatment of vein grafts and native coronary legions.

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

The MAGICAL study, which was conduct in Poland, included 60 patients with acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as STEMI). The purpose of the study was to evaluate the clinical performance of MGuard Coronary with bio-stable mesh when used in STEMI patients where percutaneous coronary intervention is the primary line of therapy. Perfect blood flow in the artery was achieved in 90% of patients, perfect blood flow into the heart muscle was achieved in 73% of patients and complete (>70%) restoration of electrocardiogram normality was achieved in 61.4% of patients. The total major adverse cardiac events rate during the six-month period following the deployment of the stents was 1.7% and after a three-year period was 8.8%.

Ongoing Clinical Trials for MGuard Coronary Bare-Metal Stent Plus Bio-Stable Mesh

Our ongoing observation study in Europe is an open registry launched in the first calendar quarter of 2009. This registry is expected to enroll up to 1,000 patients and is aimed at evaluating the performance of MGuard Coronary with bio-stable mesh in a real world population. To date, the primary countries to join are Austria, Czech Republic and Hungary. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of November 6, 2012, 548 patients of the prospective 1,000 have been enrolled in 19 sites.

Our ongoing observational study in Israel is an open registry launched in the fourth calendar quarter of 2009. This registry is expected to enroll up to 100 patients. The purpose of this study is to support local Israeli regulatory approval. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at 30 days following deployment of the stent, and the clinical follow-up will be conducted at six months following deployment of the stent. As of November 6, 2012, 86 patients of the prospective 100 have been enrolled.

In the third calendar quarter of 2010, we launched a Brazilian registry to run in 25 Brazilian sites and enroll 500 patients. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following the deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of November 6, 2012, 500 patients of the prospective 500 have been enrolled.

MASTER Randomized Trial for MGuard Coronary Compared to Bare Metal or Drug-Eluting Stents

In the second calendar quarter of 2011, we began the 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

TABLE OF CONTENTS

metal or drug-eluting stent. The detailed acute and 30 days results from the trial, which were presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference on October 24, 2012, were as follows:

The primary endpoint of post-procedure complete ST-segment resolution (restoration of blood flow to the heart muscle after a heart attack) was significantly improved in patients randomized to the MGuard Coronary stent compared to commercially-approved bare metal or drug-eluting stents (57.8% vs. 44.7%).
The MGuard Coronary stent resulted in superior rates of thrombolysis in myocardial infarction (TIMI) 3 flow, which evidences normal coronary blood flow that fills the distal coronary bed completely, as compared to commercially-approved bare metal or drug-eluting stents (91.7% vs. 82.9%), with comparable rates of myocardial blush grade 2 or 3 (83.9% vs. 84.7%) and Corrected TIMI frame count (cTFC) (17.0 vs. 18.1), markers of optimal blood flow to the heart.
Angiographic success rates (attainment of <50% final residual stenosis of the target lesion and final TIMI 3 flow) were higher in the MGuard Coronary group compared to commercially-approved bare metal or drug-eluting stents (91.7% vs 82.4%).
Mortality (0% vs. 1.9%) and major adverse cardiac events (1.8% vs. 2.3%) at 30 days post procedure were not statistically significantly different between patients randomized to the MGuard Coronary stent as opposed to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard Coronary and commercially-approved bare metal or drug-eluting stents.

In sum, the MASTER Trial demonstrated that among patients with acute STEMI undergoing emergency PCI, or angioplasty, MGuard Coronary resulted in superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution 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.

A detailed table with the results from the MASTER Trial is set forth below.

	MGuard Coronary	Bare Metal Stents/Drug Eluting Stents	p-Value
Number of Patients	217	216	
TIMI 0-1	1.8	5.6	0.01
TIMI 3	91.7	82.9	0.006
Myocardial blush grade 0-1	16.1	14.8	0.71
Myocardial blush grade 3	74.2	72.1	0.62
ST segment resolution >70	57.8	44.7	0.008
30 day major adverse cardiac event	1.8	2.3	0.75

Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI Population From Non-Comparative Study and Pooled Data.

We conducted a meta-analysis of data from four clinical trials in which MGuard Coronary was used:

The MAGICAL study, a single arm study in which 60 acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as STEMI) patients with less than 12 hours symptom onset were enrolled, as reported in Mesh Covered Stent in ST-segment Elevation Myocardial Infarction in *EuroIntervention*, 2010 and presented by D. Dudek, Extended Follow-up of the MAGICAL Trial , EuroPCR 2012;
the PISCIONE study, a single arm study in which 100 STEMI patients were enrolled, as reported in Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion in *Catheter Cardiovasc Interv*, 2009 and

presented by F. Piscione, Multicentre Experience MGuard with MGuard net Protective Stent in ST-elevation Myocardial Infarction: Long-term Results , Transcatheter Cardiovascular Therapeutics (TCT) Conference 2010 and F. Piscione, MGuard in Acute MI: Three-Year Follow-up , TCT Conference 2011;
the iMOS study, a Registry on MGuard Coronary use in the real-world population, from a study whose data was not published; and
the Jain study, which looks at a small group of 51 STEMI patients, as reported in Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent in *Catheter Cardiovasc Interv*, 2009 and presented by R. Weermckody, A Mesh Covered Stent Effectively Reduces the Risk of Digital Embolisation During Primary Percutaneous Intervention for ST Elevation Myocardial Infarction, EuroPCR 2010.

Our meta-analysis included data from the following trials:

The CADILLAC (Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications) study, which found that primary stent implantation is a preferred strategy for the treatment of acute myocardial infarction, as reported in A Prospective, Multicenter, International Randomized Trial Comparing Four Reperfusion Strategies in Acute Myocardial Infarction: Principal Report of the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) Trial in *Journal of American College of Cardiology*, 2001, Comparison of Angioplasty with Stenting, with or without Abciximab, in Acute Myocardial Infarction in *New England Journal of Medicine*, 2002, Frequency, Correlates, and Clinical Implications of Myocardial Perfusion After Primary Angioplasty and Stenting, With and Without Glycoprotein IIb/IIIa Inhibition, in Acute Myocardial Infarction in *Journal of the American College of Cardiology*, 2004 and Combined Prognostic Utility of ST-segment Recovery and Myocardial Blush After Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction in *European Heart Journal*, 2005;
The EXPORT trial which was a randomized open-label study whose primary endpoint was to evaluate flow improvement in AMI patients using either conventional stenting or aspiration followed by stenting, as reported in Systematic Primary Aspiration in Acute Myocardial Percutaneous Intervention: A Multicentre Randomised Controlled Trial of the Export Aspiration Catheter in *EuroIntervention*, 2008;
The EXPIRA trial which was a single-center study aimed to explore pre-treatment with manual thrombectomy as compared to conventional stenting, as reported in Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size: The EXPIRA (Thrombectomy with Export Catheter in Infarct-related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial in *Journal of American College of Cardiology*, 2009;
The REMEDIA trial, whose objective was to assess the safety and efficacy of the EXPORT catheter for thrombus aspiration in STEMI patients, as reported in Manual Thrombus-Aspiration Improves Myocardial Reperfusion: The Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) Trial in *Journal of American College of Cardiology*, 2005;
The Horizons-AMI (Harmonizing Outcomes with RevascularIZatiON and Stents in Acute MI), which is the largest randomized trial which compared DES to BMS in MI patients, as reported in Paclitaxel-Eluting Stents Versus Bare-Metal Stents in Acute Myocardial Infarction in *New England Journal of Medicine*, 2009, Bivalirudin in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction (HORIZONS-AMI): 1-Year Results of a Randomised Controlled Trial in *Lancet*, 2009, and Heparin Plus a Glycoprotein IIb/IIIa Inhibitor Versus Bivalirudin Monotherapy and Paclitaxel-eluting Stents Versus Bare-metal Stents in Acute Myocardial Infarction (HORIZONS-AMI): Final 3-year Results from a Multicentre, Randomised Controlled Trial in *Lancet*, 2011; and

TABLE OF CONTENTS

The TAPAS Trial which showed that thrombus aspiration before stenting benefits MI patients, as reported in Thrombus Aspiration During Primary Percutaneous Coronary Intervention in *New England Journal of Medicine*, 2009 and Cardiac Death and Reinfarction After 1 Year in the Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study (TAPAS): A 1-year Follow-up Study in *Lancet*, 2008.

The non-randomized, pooled data analysis of MGuard Coronary outcomes in STEMI population show comparable rates of thrombolysis in myocardial infarction (TIMI) 3 flow with no significant difference of the historical control as compared to MGuard Coronary (88.5% and 91.7%, respectively), while the rates of myocardial blush grade score 3 (37.3% for the historical control and 81.6% for MGuard Coronary) and ST segment resolution>70% (53.6% for the historical control and 79.1% for MGuard Coronary) are significantly better with the MGuard Coronary. MGuard Coronary also appears consistently superior at the 30 days major adverse cardiac event (8.4% for the historical control and 2.4% for MGuard Coronary) and 1 year major adverse cardiac event (13.3% for the historical control and 5.9% for MGuard Coronary) endpoints. The data appears in the following tables.

	NAME OF STUDY				
	MAGICAL	PISCIONE	iMOS	Jain	Average
Number of Patients	60	100	203	51	414 (Total)
Thrombolysis in myocardial infarction 0-1,%	0	0	1.2	0	0.6
Thrombolysis in myocardial infarction 3,%	90	85	93.5	100	91.7
Myocardial blush grade 0-1,%	3.3	0			1.2
Myocardial blush grade 3,%	73	90	80		81.6
ST segment resolution>70%,%	61	90			79.1
ST segment resolution>50%,%	88		85.4	96	87.6
30 day major adverse cardiac event,%	0	2.2	3.2		2.4
6 month major adverse cardiac events,%	0	4.5	6.0		4.6
1 year major adverse cardiac events,%		5.6	6.0	6.0	5.9
1 year target vessel revascularization		2.3	2.3	6.0	2.8
Acute Binary Resteonosis 6M,%			19.0*		19.0

	THREE YEAR FOLLOW UP STUDIES NAME OF STUDY									
	MAGICAL		PISCIONE		iMOS	Jain	Average			
Number of Patients	57 out of 60		89							
Cardiac death at 3Y	7	%	2.2	%						
Non Cardiac death at 3Y	1.8	%	6.8	%						
Re-MI at 3Y	0	%	7.9	%						
TLR at 3Y	1.8	%	Not Reported							
TVR at 3Y Include TLR	3.5	%	4.5	%						
Stroke	1.8	%	Not Reported							
Stent thrombosis Definite / Probable	0	%	2.2	%						
MACE (Cardiac death, RE-MI, TLR)	8.8	%	10.1	%						
MACCE (All death, target vessel MI, TVR, Stroke)	10.5	%	Not Reported							

TABLE OF CONTENTS

Trial	CADILLAC	Horizons-AMI	Horizons-AMI	TAPAS	TAPAS	EXPORT	EXPORT	EXPIRA	EXPIRA	REMEDIA	REMEDIA	Historical comparison	MGuard	Level of Significanc
Group	Stent + Abciximab	BMS	DES	Thrombus aspiration	control	control	TA	control	Thrombus aspiration	Thrombus aspiration	control	Average	Average	
Number of Patients	524	749	2257	535	536	129	120	87	88	50	49	5124 (total)	414 (total)	
Thrombolysis in myocardial infarction 0-1,%						3.9	2.4	1.1	0			2.1	0.6	
Thrombolysis in myocardial infarction 3,%	96.9	89.8	87.6	86	82.5	76.9	82					87.8	91.7	
Myocardial blush grade 0-1,%	48.7			17.1	26.3	31.6	27.6	40.2	11.4	32	55.1	35.2	1.2	*
Myocardial blush grade 3,%	17.4			45.7	32.2	25.4	35.8					37.3	81.6	**
ST segment resolution>70%,%	62.1			56.6	44.2			39.1	63.6	58	36.7	53.6	79.1	
ST segment resolution>50%,%						71.9	85					78.2	87.6	
30 day major adverse cardiac event,%	4.4			6.8	9.4					10	10.2	8.4	2.4	**
6 month major adverse cardiac events,%	10.2											10.2	4.6	
1 year major adverse cardiac events,%		11.9	10.5	16.6	20.3							12.8	5.9	*
Acute Binary Resteonosis 6 month,%	20.8											20.8	19.0	
1 year target vessel revascularization		8.7	5.8	12.9	11.2							8.0		
Acute Binary Resteonosis 1 year,%		21	8.2									11.5		

TABLE OF CONTENTS

Future Clinical Trials for MGuard Coronary

We expect that post-marketing trials will be conducted to further evaluate the safety and efficacy of the MGuard Coronary with bio-stable mesh in specific indications. These trials will be designed to facilitate market acceptance and expand the use of the product. We also plan to conduct a large clinical study for U.S. Food and Drug Administration approval in the United States and intend to conduct future trials to the extent necessary to meet registration requirements in key countries. In other countries outside of the United States, we believe that we generally will be able to rely upon CE Mark approval of the product, as well as the results of the U.S. Food and Drug Administration trial and MASTER Trial in order to obtain local approvals.

U.S. Food and Drug Administration Trial

Presently, none of our products may be sold or marketed 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 in order to conduct a pivotal trial. We expect that this trial will be a prospective, multicenter, randomized clinical trial. Its primary objective will be to compare the safety and the effectiveness of the MGuard Coronary stent in the treatment of de novo stenotic lesions in coronary arteries in patients undergoing primary revascularization (surgical procedure for the provision of a new, additional, or augmented blood supply to the heart) due to acute myocardial infarction with currently approved bare metal stents and drug eluting stents.

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. We are currently working with the U.S. Food and Drug Administration to resolve these deficiencies and formulate an acceptable trial design. In particular, based on the results from our MASTER trial result, we are seeking to amend the initial clinical protocol of our proposed trial to, amongst other things:

increase the sample size of the proposed trial to 1,100 patients at up to 70 sites throughout the United States and Europe;
include a more robust efficacy primary endpoint, which will be restoration of ST segment resolution of greater than 70% in patients treated with MGuard Coronary and MGuard Coronary s non-inferiority in the occurrence of target vessel failure (a composite endpoint of cardiac death, reoccurrence of a heart attack and the need for a future invasive procedure to correct narrowing of the coronary artery), as compared to other stents;
allow both drug eluting stents and bare metal stents in the control arm; and
add infarct size by cardiac magnetic resonance imaging as a powered secondary endpoint.

We intend to formally respond to the disapproval letter with these modifications in the first half of November 2012 and will request approval of an investigational device exemption application before the end of 2012. Based on discussions with the study s principal investigator and study chairman, the budget for this study is estimated to be $15.0 million and the enrollment initiation is expected to occur in the first calendar quarter of 2013. Moreover, the enrollment phase for this trial is expected to last 18 months and we expect that subjects in this trial will be followed for 12 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.

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.

TABLE OF CONTENTS

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, Belgium, 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 peripheral and carotid, for which we expect to have CE Mark approval by the first calendar quarter of 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 have applied for 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. Dr. Gregg W. Stone, director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy of New York Presbyterian Hospital/Columbia University Medical Center and the co-director of Medical Research and Education at The Cardiovascular Research Foundation is the study chairman for the MASTER Trial. Dr. Donald Cutlip, Executive Director of Clinical Investigation at the Harvard Clinical Research Institute, will provide scientific leadership of the U.S. Food and Drug Administration trials and Dr. Stone will act as principal investigator. On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled MASTER II MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction on our behalf. We will pay Harvard Clinical Research Institute, Inc., Cardio Research Foundations (CRF), as a core laboratory, and MedPass International, as our European monitoring group, an estimated aggregate fee of approximately $15.0 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

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 patent applications cover all of our existing products, and may be useful to protect

TABLE OF CONTENTS

future technology. We intend to continue patenting new technology as it is developed, and to actively pursue any infringement covered by one or more of our patents. To date, we have secured patent protection in each of the United States, South Africa and China for one patent. See Business Intellectual Property Patents).

As noted above, we previously filed patent applications for our MGuard technology in China, as part of our intended growth strategy. However, upon further consideration of the cost and resources required to achieve (and risks and costs associated with enforcing) patent protection in China, we elected to prioritize our pursuit of growth opportunities in other countries and, as such, have ceased our growth efforts in China for the current time period. We intend to reevaluate our strategy towards commercialization of our MGuard technology in China in the future.

Competition

The stent industry is highly competitive. The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc. Due to ongoing consolidation in the industry, there are high barriers to entry for small manufacturers in both the European and the U.S. markets. However, we believe that the European market is somewhat more fragmented, and small competitors appear able to gain market share with greater ease.

In the future, we believe that physicians will look to next-generation stent technology to compete with existing therapies. These new technologies will likely include bio-absorbable stents, stents that are customizable for different lesion lengths, stents that focus on treating bifurcated lesions, and stents with superior polymer and drug coatings. Some of the companies developing new stents are The Sorin Group, Xtent, Inc., Cinvention AG, OrbusNeich, Biotronik SE & Co. KG, Svelte Medical Systems, Inc., Reva Inc. and Stentys SA, among others. To address current issues with drug-eluting stents, The Sorin Group and Cinvention AG have developed stents that do not require a polymer coating for drug delivery, thereby expanding the types of drugs that can be used on their respective stents. OrbusNeich has addressed the problem differently, developing a stent coated with an antibody designed to eliminate the need for any drug at all. Xtent, Inc. has been concentrating on a stent that can be customized to fit different sized lesions, so as to eliminate the need for multiple stents in a single procedure. Biotronik SE & Co. KG is currently developing bio-absorbable stent technologies, and Abbott Laboratories is currently developing a bio-absorbable drug-eluting stent. These are just a few of the many companies working to improve stenting procedures in the future as the portfolio of available stent technologies rapidly increases. As the market moves towards next-generation stenting technologies, minimally invasive procedures should become more effective, driving the growth of the market in the future. We plan to continue our research and development efforts in order to be at the forefront of the acute myocardial infarction solutions.

According to the 2011 MEDTECH OUTLOOK produced by the BMO Capital Markets on January 3, 2011, the worldwide stent market is dominated by four major players, with a combined total market share of approximately 96%. Within the bare metal stent market and drug-eluting stent market, the top four companies have approximately 92% and 98% of the market share, respectively. These four companies are Abbott Laboratories, Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to the further growth of MGuard is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do.

In addition to the challenges from our competitors, we face challenges related specifically to our products. None of our products is currently approved by the U.S. Food and Drug Administration. Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard products 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. Furthermore, our rights to our intellectual property with respect

TABLE OF CONTENTS

to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard products based on one or more of these patents, and/or will allege misappropriation of their proprietary confidential information or other intellectual property.

We note that an additional challenge facing our products comes from drug-eluting stents. Over the last decade, there has been an increasing tendency to use drug-eluting stents in PCI, with a usage rate of drug-eluting stents in PCI approaching 70-80% in some countries, even though drug-eluting stents do not address thrombus management in acute myocardial infarction. A recent HORIZONS-AMI trial that compared drug-eluting stents to bare-metal stents in STEMI patients failed to show any benefit of drug-eluting stents as compared to bare-metal stents with regard to safety (death, re-infarction, stroke, or stent thrombosis), but showed the 1 year target vessel revascularization (TLR) rate for drug-eluting stent patients was only 4.6%, as compared to 7.4% for patients with bare-metal stents. However, based on data from over 350 patients across three clinical trials, the TLR rate for MGuard Coronary was 2.8%. (This data is comprised of: (i) a TLR rate of 2.3% for a 100-patient study, as reported in Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion in *Catheter Cardiovasc Interv*, 2009; (ii) a TLR rate of 2.3% for a sub-group of 203 STEMI patients from the International MGuard Observational Study; and (iii) a TLR rate of 6.0% for a group of 51 heart attack patients, as reported in Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent in *Catheter Cardiovasc Interv*, 2009).

Another challenge facing the MGuard products is that placing the stent at the entrance to large side branches, known as jailing large side branches, is not recommended with the MGuard Coronary stent, because there is a risk of thrombosis. Jailing requires the need to cross the stent with guidewire and to create an opening with the balloon to allow proper flow, which can be achieved with lower risk by using other bare-metal stents.

Research and Development Expenses

During each of the six months ended June 30, 2012 and the twelve months ended December 31, 2011, 2010 and 2009, we spent approximately $2.6 million, $2.5 million, $1.3 million and $1.3 million, respectively, on research and development.

Sales and Marketing

Sales and Marketing

In October 2007, MGuard Coronary with a bio-stable mesh received CE Mark approval in the European Union, and shortly thereafter was commercially launched in Europe through local distributors. We are also in negotiations with additional distributors in Europe, Asia and Latin America and are currently selling our MGuard Coronary with a bio-stable mesh in more than 30 countries.

Until U.S. Food and Drug Administration approval of our MGuard Coronary with a bio-stable mesh, which we are targeting for 2015, we plan to focus our marketing efforts primarily on Europe, Asia and Latin America. Within Europe, we have focused on markets with established healthcare reimbursement from local governments such as Russia, Italy, Germany, France, Greece, Austria, Hungary, Poland, Slovenia, Czech Republic and Slovakia.

In addition to utilizing local and regional distributor networks, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We plan to work with leading physicians to enhance our marketing efforts. As sales volume increases, we may engage in direct sales in certain geographic markets.

Product Positioning

The MGuard Coronary has initially penetrated the market by entering market segments with indications that present high risks of embolic dislodgement, notably acute myocardial infarction and saphenous vein graft coronary interventions. The market penetration of the MGuard Coronary in 2011 was minimal, with total sales

TABLE OF CONTENTS

in the twelve months ended December 31, 2011 of approximately $6.0 million representing less than 1% of the total sales of the acute myocardial infarction solutions market and the market penetration for the six months ended June 30, 2012 was also minimal, with total sales in the six months ended June 30, 2012 of approximately $2.1 million representing less than 1% of the total sales of the acute myocardial infarction solutions market.

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, and drug-eluting stents, which have a high rate of late stent thrombosis, require administration of anti-platelet drugs for at least one year post procedure and are more costly than bare-metal stents. We are marketing our platform technology, MGuard Coronary, as a superior and cost effective solution to these currently unmet needs of interventional cardiologists. We believe our MGuard Coronary technology is clinically superior to bare-metal stents because it provides embolic protection during and post-procedure. We believe our MGuard Coronary technology is clinically superior to drug-eluting stents, due to its lower stent thrombosis rate and protection from embolic showers during and post-procedure.

In addition to the advantages of the MGuard Coronary technology that we believe to exist, the MGuard Coronary technology maintains the deliverability, crossing profile, and dilatation pressure of a conventional stent, and interventional cardiologists do not have to undergo any training before utilizing the product.

Insurance Reimbursement

In most countries, a significant portion of a patient s medical expenses is covered by third-party payors. Third-party payors can include both government funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, the vast majority of payors have similarly established policies. All of the MGuard products sold to date have been designed and labeled in such a way as to facilitate the utilization of existing reimbursement codes, and we intend to continue to design and label our products in a manner consistent with this goal.

While most countries have established reimbursement codes for stenting procedures, certain countries may require additional clinical data before recognizing coverage and reimbursement for the MGuard products or in order to obtain a higher reimbursement price. In these situations, we intend to complete the required clinical studies to obtain reimbursement approval in countries where it makes economic sense to do so.

In the United States, once the MGuard Coronary with bio-stable mesh is approved by the U.S. Food and Drug Administration, it will be eligible for reimbursement from the Centers for Medicare and Medicaid Services, which serve as a benchmark for all reimbursement codes. While there is no guarantee these codes will not change over time, we believe that the MGuard Coronary will be eligible for reimbursement through both governmental healthcare agencies and most private insurance agencies in the United States once it is approved by the U.S. Food and Drug Administration.

Intellectual Property

Patents

We have filed nine patent applications in the United States (including one that is still in the Patent Cooperation Treaty international phase) covering aspects of our MGuard technology. We have filed corresponding patent applications in Canada, China, Europe, Israel, India and South Africa, for an aggregate total of 35 patents and pending applications. These patent applications are directed to cover percutaneous therapy, knitted stent jackets, stent and filter assemblies,

in vivo filter assembly, optimized stent jackets, stent apparatuses for treatment via body lumens and methods of use, stent apparatuses for treatment via body lumens and methods of manufacture and use, and stent apparatuses for treatment of body lumens, among others. In lay terms, these patent applications generally cover three aspects of our products: the mesh sleeve with and without a drug, the product, and the delivery mechanism of the stent. On October 27, 2010, our patent application pertaining to Stent Apparatus for Treatment via Body Lumens and Method of Use , South Africa patent application 2007/10751, was issued as South Africa Patent No. 2007/10751. On October 25, 2011, our patent application pertaining to In Vivo Flter Assembly , U.S. Patent Application 11/582,354, was issued as U.S. Patent 8,043,323. On June 13, 2012, our patent application pertaining to Filter Assemblies , China Patent Application No. 200780046659.9, was issued as China Patent No. ZL200780046659.9. None of

TABLE OF CONTENTS

the other patent applications has been granted to date. We believe one or more pending patent applications, upon issuance, will cover each of our existing products. We also believe that the patent applications we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, if issued as patents with claims substantially in their present form, would likely create a significant barrier for another company seeking to use similar technology.

To date, we are not aware of other companies that have patent rights to a micron fiber, releasable knitted fiber sleeve over a stent. However, larger, better funded competitors own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange that might be alleged to cover one or more of our products. Stent manufacturers have historically engaged in significant litigation, and we could be subject to claims of infringement of intellectual property from one or more competitors. Although we believe that any such claims based on patents of which we are currently aware would be un-founded, such litigation would divert attention and resources away from the development and/or commercialization of MGuard stents. Furthermore, we may be subject to claims of infringement of patents of which we are currently unaware. Other manufacturers or other parties may also challenge the intellectual property that we own, or may own in the future. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

Trademarks

We use the InspireMD and MGuard trademarks in connection with our products. We have registered these trademarks in Europe. The trademarks are renewable indefinitely, so long as we continue to use the mark in Europe and make the appropriate filings when required.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the European Union CE Mark, the U.S. Food and Drug Administration and other corresponding foreign agencies.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain U.S. Food and Drug Administration market authorization. These differences may affect the efficiency and timeliness of international market introduction of our products. For countries in the European Union, medical devices must display a CE Mark before they may be imported or sold. In order to obtain and maintain the CE Mark, we must comply with the Medical Device Directive 93/42/EEC and pass initial and annual facilities audit inspections to ISO 13485 standards by an European Union inspection agency. We have obtained ISO 13485 quality system certification and the products we currently distribute into the European Union display the required CE Mark. In order to maintain certification, we will be required to pass annual facilities audit inspections conducted by European Union inspectors.

As noted below, we currently have distribution agreements for our products with distributors in the following countries: Italy, Germany, Austria, Czech Republic, Slovakia, France, Slovenia, Greece, Cyprus, Portugal, Spain, Poland, Hungary, Estonia, Ukraine, Holland, Russia, Latvia, Brazil, Chile, Costa Rica, Mexico, Argentina, Colombia, India, Sri Lanka, South Africa, Pakistan, Israel, Uruguay, Venezuela, Ireland, Belarus and Egypt. We are subject to governmental regulation in each of these countries and we are not permitted to sell all of our products in each of these

countries. While each of the European Union member countries accepts the CE Mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we believe that each of the above-listed countries that is not a member of the European Union accepts the CE Mark as its primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of the MGuard Prime version of the MGuard Coronary product. Additionally, in Canada, we are required to pass annual facilities audit inspections performed by Canadian inspectors. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America.

TABLE OF CONTENTS

We believe that each country that we are targeting also accepts the CE Mark as its primary requirement for marketing approval. We intend that the results of the MASTER Trial will satisfy any additional governmental regulatory requirements in each of the countries where we currently distribute our products and in any countries that we are currently targeting for expansion. However, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

The MGuard Prime version of the MGuard Coronary product received CE Mark approval in the European Union in October 2010 and marketing approval in Israel in September 2011. We are currently seeking marketing approval for the MGuard Prime version of the MGuard Coronary product in Brazil, Malaysia, Mexico, Russia, Serbia, Singapore, Argentina, India, Sri Lanka, Pakistan, South Korea, Ukraine, Belarus and Canada. We are focused on seeking marketing approval in these countries because we believe that these countries represent the strongest opportunities for us to grow with respect to our sales. We have determined that other countries with better organized and capitalized healthcare systems may not present us the same opportunities for growth due to the lack of use of stents in treatment of cardiac episodes and less advantageous healthcare reimbursement policies, among other reasons. While we understand that each of the countries in which we are seeking marketing approval for the MGuard Prime version of the MGuard Coronary product accepts the CE Mark as its primary requirement for marketing approval and does not to our understanding require any additional tests, each country does have some additional regulatory requirements for marketing approval, as we have been informed by our distributors, who are responsible for obtaining marketing approval for our products. More specifically, for example, the approval process in Malaysia requires us to submit an application for regulatory approval, which we anticipate will be granted approximately three months later. For the approval process in Mexico, we need to submit an application for regulatory approval, which we anticipate will be granted approximately twelve months later. For the approval process in Serbia, we need to submit an application for regulatory approval, which we anticipate will be granted approximately four months later. For the approval process in Singapore, we need to submit an application for regulatory approval, which we anticipate will be granted approximately ten months later. For the approval process in Argentina, we need to submit an application for regulatory approval, which we anticipate will be granted approximately twelve months later. For the approval process in India, we need to submit an application for regulatory approval, which we anticipate will be granted in November or December 2012. For the approval process in Sri Lanka, we need to submit an application for regulatory approval, which we anticipate will be granted in approximately six to twelve months. For the approval process in Pakistan, we need to submit an application for regulatory approval, which we anticipate will be granted in approximately six to twelve months. For the approval process in South Korea, we need to submit an application for regulatory approval, which we anticipate will be granted in approximately two years. For the approval process in Ukraine, we need to submit an application for regulatory approval, which we anticipate will be granted approximately six months later. For the approval process in Belarus, we need to submit an application for regulatory approval, which we anticipate will be granted approximately six months later. For the approval process in Canada, we need to submit an application for regulatory approval, which we anticipate will be granted approximately twelve months later. In Israel, where we received marketing approval in September 2011, we will be subject to annual renewal of our marketing approval. Regulators in Israel may request additional documentation or other materials and results of studies from medical device manufacturers as part of the renewal process. Generally, however, the annual renewal of marketing approval is given automatically, barring a material change in circumstances or results. In Russia, we received market approval in February 2012. In Chile, we received market approval for our previous distributor in December 2010. We have terminated our relationship with our previous distributor in Chile, however, and once we enter into a relationship with a new distributor, we will be required to submit a new application for regulatory approval in Chile, which we anticipate will be granted approximately twelve months after our submission for approval.

For the approval process in Brazil, we must comply with Brazilian Good Manufacturing Practice, or GMP, quality system requirements. ANVISA, Brazil s regulatory agency, must conduct an inspection of the manufacturing of the MGuard Prime version of the MGuard Coronary product to determine compliance with Brazil GMP regulations. Upon successful completion of an audit, ANVISA will then issue the GMP certificate

TABLE OF CONTENTS

necessary to register a medical device in Brazil. Once we receive the necessary GMP certificate, we can apply for regulatory approval. We anticipate that the approval process in Brazil will take between one and two years.

Please refer to the table below setting forth the approvals and sales for original stainless steel based MGuard Coronary product and the cobalt-chromium based MGuard Prime version of the MGuard Coronary product on a country-by-country basis.

Approvals and Sales of the Original MGuard Coronary and the MGuard Prime version of the MGuard Coronary on a Country-by-Country Basis

Countries	Original MGuard Approval	Original MGuard Sales	MGuard Prime Approval	MGuard Prime Sales
Argentina	Y	Y	N	N
Austria	Y	Y	Y	Y
Brazil	Y	Y	N	N
Chile	N (1)	Y	N	N
Colombia	Y	Y	N	N
Costa Rica	Y (3)	Y	N	N
Cyprus	Y	Y	Y	N
Czech Rep	Y	Y	Y	N
UK	Y	N	Y	N
Estonia	Y	Y	Y	Y
France	Y	Y	Y	Y
Germany	Y	Y	Y	Y
Greece	Y	Y	Y	Y
Holland (Netherlands)	Y	Y	Y	Y
Hungary	Y	Y	Y	Y
India	Y	Y	N	N
Israel	Y	Y	Y	Y
Italy	Y	Y	Y	Y
Latvia	Y	Y	Y	Y
Lithuania	Y	Y	Y	N
Malaysia	N	N	N	N
Mexico	Y	Y	N	N
Pakistan	Y (3)	Y	N	N
Poland	Y	Y	Y	Y
Portugal	Y	Y	Y	N
Russia	Y	Y	Y	Y
Serbia	N	N	N	N
Singapore	N	Y (2)	N	N
Slovakia	Y	Y	Y	N
Slovenia	Y	Y	Y	Y

South Africa	Y [3]	Y	N	N
Spain	Y	Y	Y	Y
Sri Lanka	Y [3]	Y	N	N
Ukraine	Y	Y	N	N

(1) We terminated our relationship with our previous distributor in Chile and we will be required to obtain regulatory approval upon our selection of a new distributor in Chile.

(2) At time the sales were made, we satisfied the regulatory requirements in Singapore. The regulatory requirements in Singapore were subsequently changed and we no longer meet these requirements.

(3) We believe that we have regulatory approval for the MGuard Coronary product in this country, based upon information from our distributor in such country, who was responsible for obtaining the regulatory approval for the MGuard Coronary product. However, the certificate evidencing regulatory approval is held by our distributor and we cannot guarantee that it is in full force and effect.

TABLE OF CONTENTS

In the United States, the medical devices that will be manufactured and sold by us will be subject to laws and regulations administered by the U.S. Food and Drug Administration, including regulations concerning the prerequisites to commercial marketing, the conduct of clinical investigations, compliance with the Quality System Regulation and labeling. We anticipate that our MGuard Coronary product with bio-stable mesh product will be classified as a Class III medical device by the U.S. Food and Drug Administration.

A manufacturer may seek market authorization for a new medical device through the rigorous Premarket Approval application process, which first requires that the U.S. Food and Drug Administration determine that the device is safe and effective for the purposes intended.

We will also be required to register with the U.S. Food and Drug Administration as a medical device manufacturer. As such, our manufacturing facilities will be subject to U.S. Food and Drug Administration inspections for compliance with Quality System Regulation. These regulations will require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As a medical device manufacturer, we will further be required to comply with U.S. Food and Drug Administration requirements regarding the reporting of adverse events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. U.S. Food and Drug Administration regulations also govern product labeling and prohibit a manufacturer from marketing a medical device for unapproved applications. If the U.S. Food and Drug Administration believes that a manufacturer is not in compliance with the law, it can institute enforcement proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the manufacturer, its officers and employees.

Customers