InspireMD, Inc.
Form S-1/A
December 22, 2011

As filed with the Securities and Exchange Commission on December 22, 2011

SEC File No. 333-174948

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

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AMENDMENT NO. 5
TO
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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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.)

3 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.
3 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

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

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

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

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

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

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

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

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.

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.

SUBJECT TO COMPLETION, DATED DECEMBER 22, 2011

PRELIMINARY PROSPECTUS

InspireMD, Inc.

414,942 Shares of Common Stock Underlying Warrants

This prospectus relates to the resale of up to 414,942 shares of our common stock to be offered by the selling stockholders upon the exercise of outstanding common stock purchase warrants by the selling stockholders.

The selling stockholders may sell shares of common stock from time to time in the principal market on which our common stock is traded at the prevailing market price or in privately negotiated transactions. See “Plan of Distribution” which begins on page 60.

We will not receive any of the proceeds from the sale of common stock by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholders. We intend to use those proceeds, if any, for general corporate purposes. We will pay the expenses of registering these shares.

All expenses of registration incurred in connection with this offering are being borne by us, but all selling and other expenses incurred by the selling stockholders will be borne by the selling stockholders.

Our common stock is quoted on the regulated quotation service of the OTC Bulletin Board under the symbol “NSPR.OB”. On December 21, 2011, the last reported sale price of our common stock as reported on the OTC Bulletin Board was $1.70 per share.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Investing in our common stock is highly speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties in the section entitled “Risk Factors” beginning on page 5 of this prospectus before making a decision to purchase our stock.

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

The date of this prospectus is , 2011

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We 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 making an offer to sell these securities in any jurisdiction where 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.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our historical financial statements and related notes included elsewhere in this prospectus or any accompanying prospectus supplement before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our" and "us" for periods prior to the closing of our share exchange 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, and references to "we," "our" and "us" for periods subsequent to the closing of the share exchange transactions refer to InspireMD, Inc., a publicly traded Delaware corporation, and its direct and indirect subsidiaries, including InspireMD Ltd.

Overview

We are an innovative 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 (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 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, seamless and complete solution for these patients. For the year ended December 31, 2010, our total revenue was approximately $4.9 million and our net loss was approximately $3.4 million. For the nine months ended September 30, 2011, our total revenue was $4.7 million and our net loss was approximately $6.4 million.

MGuardTM Sleeve – Microscopic View

We intend to use our MGuard™ technology in a broad range of coronary related situations in which complex lesions are required and make it an industry standard for treatment of acute coronary syndromes. We believe that patients will benefit from a cost-effective alternative with a greater 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.

1

Table of Contents

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 Canada, Southeast Asia, India and Latin America.

Our initial MGuard™ products incorporated a stainless steel stent. We replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as MGuard Prime™. We believe the new platform will 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.

MGuard Prime™ 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 MGuard™ clinical trial results to market MGuard Prime™. However, we face a number of challenges to the further growth of MGuard™. 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 are 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™ 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. Furthermore, our rights to our intellectual property with respect to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard™ stent 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™ are to both our initial product, MGuard™, and MGuard Prime™, as applicable.

Recent Events

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 and, as such, the information with respect to our common stock in this prospectus and the accompanying financial statements and related notes does not give effect to any reverse stock split.

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 "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 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.

Table of Contents

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 50,666,663 shares of 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.

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 7,500,000 shares 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.

Contemporaneously with the foregoing transactions, we completed a private placement pursuant to which we sold 6,454,002 shares of common stock and five-year warrants to purchase up to 3,226,999 shares of common stock at an exercise price of $1.80 per share for aggregate cash proceeds of $9,013,404 and the cancellation of $667,596 of indebtedness held by investors. In addition, on April 18, 2011 and April 21, 2011, we completed private placements pursuant to which we sold an aggregate of 983,334 shares of common stock and five-year warrants to purchase up to 491,667 shares of common stock at an exercise price of $1.80 per share for aggregate cash proceeds of $1,475,000.

Before the share exchange transactions, our corporate name was Saguaro Resources, Inc., and our trading symbol was SAGU.OB. On March 28, 2011, we changed our corporate name to InspireMD, Inc. and on April 11, 2011 our trading symbol was changed to NSPR.OB.

The Offering

Common stock offered by the selling stockholders:	414,942 shares of our common stock to be offered by the selling stockholders upon the exercise of outstanding common stock purchase warrants.
Common stock outstanding prior to the offering:	68,178,947
Common stock outstanding after this offering:	68,593,889 (1)
Use of proceeds:	We will not receive any proceeds from the sale of the common stock offered by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholders. We intend to use those proceeds, if any, for general corporate purposes.
Offering Price:	All or part of the shares of common stock offered hereby may be sold from time to time in amounts and on terms to be determined by the selling stockholders at the time of sale.

OTC Bulletin Board symbol:	NSPR.OB
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 5 of this prospectus before deciding whether or not to invest in shares of our common stock.

Table of Contents

(1) The number of shares of common stock outstanding after the offering is based upon 68,178,947 shares outstanding as of December 21, 2011 and assumes the exercise of all warrants with respect to those shares being registered for resale pursuant to the registration statement of which this prospectus forms a part.

The number of shares of common stock outstanding after this offering excludes:

- 7,723,583 shares of common stock issuable upon the exercise of currently outstanding warrants with exercise prices ranging from $1.23 to $1.80 per share and having a weighted average exercise price of $1.63 per share;
- 12,298,587 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.0 to $2.60 and having a weighted average exercise price of $1.09 per share; and
- 6,684,047 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan.

Table of Contents

Risk Factors

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should carefully consider the risks described below and the financial and other information included in this prospectus. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business

We expect to derive our revenue from sales of our MGuardTM 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 could 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. 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 patents may not provide us with commercially meaningful protection for our products or afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us 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.

Table of Contents

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, patent applications in the U.S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. 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 U.S. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in 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 or enforceability of our patents. If a court decides that such patents are not valid, not enforceable or of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patents 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 provide us with freedom to operate unimpeded by the patent rights of others.

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 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. As a result, there can be no assurance that we will ever generate substantial revenues or sustain profitability.

Table of Contents

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our MGuard™ stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard™ stent until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard™ stent for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

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

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.

Table of Contents

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™ stent have involved procedures performed by physicians who are technically proficient and are high-volume stent users. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our MGuard™ 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™ 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 5 employees. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

Table of Contents

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the U.S., 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 U.S., 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 U.S. The U.S. Food and Drug Administration enforces the Quality System Regulation through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the U.S. Food and Drug Administration and will have to successfully complete such inspections before we receive U.S. regulatory approval for our products. Failure by us or one of our suppliers to comply with statutes and regulations administered by the U.S. Food and Drug Administration and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

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

- injunctions; and
- criminal prosecution.

Table of Contents

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 U.S., 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.

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 U.S. 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.

Table of Contents

The medical device market is highly competitive. We compete with many medical service companies in the U.S. 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 right to our intellectual property.

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 and related claims may have already been filed against us of which we are not aware. A number of these 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, or a patent infringement 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.

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.

Table of Contents

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 our 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, including our chief executive officer, Ofir Paz, and president, Asher Holzer, each of whom 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, and sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel, our operations may be jeopardized and our results of operations may be materially and adversely affected.

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

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

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;

- greater risk of uncollectible accounts;

Table of Contents

- 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; 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 U.S. and in international markets. There is increasing pressure by governments worldwide to contain health care costs by limiting both the coverage and the level of reimbursement for therapeutic products and by refusing, in some cases, to provide any coverage for products that have not been approved by the relevant regulatory agency. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare

products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and future revenues, if any, would be adversely affected.

Table of Contents

In the U.S., 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 U.S. 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™ stent in the U.S., 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 U.S., 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 and results of operations.

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 Security Law of 1968. Section 15 to the Israeli Security Law of 1968 requires the filing of a prospectus with the Israel Security Authority and the delivery thereof to purchasers in connection with an offer or sale of securities to more than 35 parties during any 12 month period. We allegedly issued securities to more than 35 investors during certain 12-month periods, ending in October 2008. Our wholly-owned subsidiary, InspireMD Ltd, a private company incorporated under the laws of the State of Israel, applied for a no-action determination from the Israel Security Authority on February 14, 2011 in connection with the foregoing. To date, the Israel Security 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 Security 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 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 current stockholders' ownership interests.

We will need to raise additional capital in the future, which may not be available on reasonable terms or at all. We recently raised approximately $10,500,000 and expect that such proceeds, together with our income, will be insufficient to fully realize all of our business objectives. For instance, we will need to raise additional funds to accomplish the following:

Table of Contents

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 current 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.

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

All of our assets are located outside the U.S. and we do not currently maintain a permanent place of business within the U.S. In addition, most of our directors and all of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the U.S. 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 U.S. or any state thereof. 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.

Risks Related to Our Organization and Our Common Stock

We are subject to financial reporting and other requirements for which our accounting, internal audit and other management systems and resources may not be adequately prepared.

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. Section 404 will require 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 will place significant demands on our management, administrative, operational, internal audit and accounting resources. We are presently upgrading our systems; implementing financial and management controls, reporting systems and procedures; implementing an internal audit function; and we have hired additional accounting, internal audit and finance staff. If we are unable to accomplish these objectives in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. 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.

Because we became public by means of a “reverse merger,” we may not be able to attract the attention of major brokerage firms.

There may be risks associated with us becoming public through a “reverse merger” with a shell company. Although the shell company did not have recent or past operations or assets and we performed a due diligence review of the shell company, there can be no assurance that we will not be exposed to undisclosed liabilities resulting from the prior operations of the shell company. Securities analysts of major brokerage firms and securities institutions may also not provide coverage of us because there were no broker-dealers who sold our stock in a public offering that would be incentivized to follow or recommend the purchase of our common stock. The absence of such research coverage could limit investor interest in our common stock, resulting in decreased liquidity. No assurance can be given that established brokerage firms will, in the future, want to cover our securities or conduct any secondary offerings or other financings on our behalf.

Table of Contents

Our stock price may be volatile after this offering, which could result in substantial losses for investors.

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

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

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

We are subject to penny stock rules which will make the shares of our common stock more difficult to sell.

We are subject to the Securities and Exchange Commission's "penny stock" rules since our shares of common stock sell below $5.00 per share. Penny stocks generally are equity securities with a per share price of less than $5.00. The penny stock rules require broker-dealers to deliver a standardized risk disclosure document prepared by the Securities and Exchange Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information must be given to the customer orally or in writing prior to completing the transaction and must be given to the customer in writing before or with the customer's confirmation.

Table of Contents

In addition, the penny stock rules require that prior to a transaction the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. The penny stock rules are burdensome and may reduce purchases of any offerings and reduce the trading activity for shares of our common stock. As long as our shares of common stock are subject to the penny stock rules, the holders of such shares of common stock may find it more difficult to sell their securities.

There is, at present, only a limited market for our common stock and we cannot ensure investors that an active market for our common stock will ever develop or be sustained.

Our shares of common stock are thinly traded. Due to the illiquidity, the market price may not accurately reflect our relative value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. Because our common stock is so thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price and investors may not be able to liquidate their investment in us at all or at a price that reflects the value of the business. In addition, our common stock currently trades on the OTC Bulletin Board, which generally lacks the liquidity, research coverage and institutional investor following of a national securities exchange like the NYSE Amex, the New York Stock Exchange or the Nasdaq Stock Market. While we intend to list our common stock on a national securities exchange once we satisfy the initial listing standards for such an exchange, we currently do not, and may not ever, satisfy such initial listing standards.

Our board of directors can authorize the issuance of preferred stock, which could diminish the rights of holders of our common stock, and make a change of control of us more difficult even if it might benefit our stockholders.

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. Upon the effectiveness of the registration statement of which this prospectus forms a part, 414,942 shares of our common stock will become freely tradable. In addition, an additional approximately 59,278,947 shares of our common stock will become saleable under Rule 144 following April 6, 2012. As these shares and as additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

In addition, if our stockholders sell substantial amounts of our common stock in the public market, upon the expiration of any statutory holding period under Rule 144, upon the expiration of lock-up periods applicable to outstanding shares, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also 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.

Table of Contents

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 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 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 the Nasdaq Capital Market or to meet the continued listing standards of the Nasdaq Capital Market after a reverse stock split.

The Nasdaq Capital Market has numerous initial listing requirements applicable to the listing of our common stock and its continued listing thereafter. While we believe we currently meet these standards, other than the minimum bid price requirement of more than $4.00 per share, we cannot assure you that our common stock will be accepted for listing on the Nasdaq Capital Market following the 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.

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," "estima 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:

- adverse economic conditions and/or intense competition;
- loss of a key customer or supplier;
- entry of new competitors and products;
- adverse federal, state and local government regulation, in the U.S., Europe or Israel;
- failure to adequately protect our intellectual property;
- inadequate capital;
- technological obsolescence of our products;
- technical problems with our research and products;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans;
- loss or retirement of key executives and research scientists and other specific risks; and
- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives.

You should review carefully the section entitled "Risk Factors" beginning on page 5 of this prospectus for a discussion of these and other risks that relate to our business and investing in shares of our common stock.

Use Of Proceeds

All shares of our common stock offered by this prospectus are being registered for the accounts of the selling stockholders and we will not receive any proceeds from the sale of these shares.

The shares of common stock offered by this prospectus are issuable upon the exercise of common stock purchase warrants. As such, if a selling stockholder exercises all or any portion of its warrants on a cash basis, we will receive the aggregate exercise price paid by such selling stockholder in connection with any such warrant exercise. The maximum amount of proceeds we would receive upon the exercise of all the warrants on a cash basis would be

approximately $747,000.00. However, the selling stockholders may also exercise their warrants through a cashless exercise. In the event a selling stockholder exercises a warrant through a cashless exercise, we will not receive any proceeds from such exercise. We expect to use the proceeds received from the exercise of the warrants, if any, for general working capital purposes.

Table of Contents

Market For Our Common Stock And Related Stockholder Matters

Our common stock has been quoted on the OTC Bulletin Board since April 11, 2011 under the symbol NSPR.OB. 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.

Fiscal Year 2011	High	Low
Second Quarter	$2.89	$1.75
Third Quarter	$2.74	$1.80
Fourth Quarter (through December 21, 2011)	$2.59	$1.60

The last reported sales price of our common stock on the OTC Bulletin Board on December 21, 2011, was $1.70 per share. As of December 21, 2011, there were approximately 197 holders of record 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.

Management's Discussion And Analysis Of Financial Condition And Results Of Operation

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 50,666,663 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 are being 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.

Recent Events

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 and, as such, the information with respect to our common stock in this prospectus and the accompanying financial statements and related notes does not give effect to any reverse stock split.

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 "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 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.

Table of Contents

Critical Accounting Policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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 revenue recognition including provision for returns, legal contingencies and estimation of the fair value of share-based compensation and convertible debt.

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 Germany and Israel, 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."

Table of Contents

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 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. To date, inventory adjustments have not been material. In 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 when product returns can be reliably estimated. When product returns can be reliably estimated a provision is recorded, based on historical experience, and deducted from sales. 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 revenues and related direct costs are eliminated, as the products are deemed unsold. Accordingly, both related revenues and costs are deferred, and presented under "Deferred revenues" and "Inventory on consignment", respectively.

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 expensed 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.

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, 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.

Table of Contents

Results of Operations

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010

Revenues. For the three months ended September 30, 2011, total revenue increased approximately $0.8 million, or 62.4%, to approximately $2.0 million from approximately $1.2 million during the same period in 2010. The $0.8 million increase was due to an increase in volume of approximately $0.7 million, or approximately 55.9%, and by an increase of prices of approximately $0.1 million, or approximately 6.5%. The following is an explanation of the approximately $0.8 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $1.0 million offset by a net decrease in deferred revenues of approximately $0.2 million.

For the three months ended September 30, 2011, total gross revenue increased by approximately $0.9 million, or 87.8%, to approximately $2.0 million as compared to approximately $1.1 million during the same period in 2010. This increase in total gross revenue is predominantly volume based, accounting for approximately $0.8 million or approximately 80.3%, and an increase of prices of approximately $0.1 million, or approximately 7.5%. In general, we focused on opening new markets, such as Russia and the Ukraine, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuardTM. With respect to individual markets, this increase in gross revenue is mainly attributable to an increase of approximately $0.2 million of gross revenue from our distributor in Brazil, 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 new distributor in Russia, an increase of approximately $0.1 million of gross revenue from our new distributor in the Ukraine, an increase of approximately $0.1 million of gross revenue from our distributor in Mexico, an increase of approximately $0.1 million of gross revenue from our distributor in Italy, an increase of approximately $0.1 million of gross revenue from our distributor in Spain and an increase of approximately $0.1 million of gross revenue from our distributor in Israel. This increase was partially offset by a decrease of approximately $0.3 million in gross revenue from our distributor in Germany and a decrease of approximately $0.1 million from our distributor in Romania. We also shipped and recognized gross revenue for approximately $0.3 million more from our remaining distributors during the three months ended September 30, 2011, as compared to the same period in 2010.

For the three months ended September 30, 2011, net deferred revenue recognized during the period decreased by approximately $0.2 million, or 102.1%, to approximately $(4,000) and from approximately $0.2 million during the same period in 2010. The decrease was volume based. 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, no customers had revenues deferred until the three months ended September 30, 2011.

For the three months ended September 30, 2011, our net deferred revenue of $(4,000) consisted of only a provision for sales return included in "accounts payable and accrual - other." For the three months ended September 30, 2010, net deferred revenue of approximately $0.2 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Israel of approximately $0.1 million and our distributor in Poland of approximately $50,000.

Gross Profit. For the three months ended September 30, 2011, gross profit (revenue less cost of revenues) increased approximately 79.0%, or approximately $0.5 million, to approximately $1.2 million from approximately $0.7 million during the same period in 2010. Gross margin increased from 54.1% in the three months ended September 30, 2010 to 59.7% in the three months ended September 30, 2011. We were able to improve our gross margin because of reduced production cost per stent driven by economies of scale, as well as an increase in average price per stent. For the three months ended September 30, 2011, our average selling price per stent recognized in revenue was $624, and we recognized the sale of 3,186 stents, compared to an average price of $577 per stent and 2,120 stents recognized in revenue for the same period in 2010. The higher average price per stent for the three months ended September 30, 2011 was driven by sales of MGuard Prime, which was launched in 2011 and is priced on average $171 more versus

the average price of MGuard per stent. Our cost of goods sold per stent decreased from an average of $265 per stent recognized in revenue for the three months ended September 30, 2010 to an average of $251 per stent for the same period in 2011.

Research and Development Expense. For the three months ended September 30, 2011, research and development expense increased 179.1% to approximately $0.5 million from approximately $0.2 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.2 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately $0.1 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately $0.1 million), and an increase in R&D related salaries of approximately $0.2 million relating to the above mentioned clinical studies. Research and development expense as a percentage of revenue increased to 27.5% for the three months ended September 30, 2011 from 16.0% in the same period of 2010.

Selling and Marketing Expense. For the three months ended September 30, 2011, selling and marketing expense increased 8.2% to approximately $0.3 million, from approximately $0.28 million during the same period in 2010. The increase in cost resulted primarily from approximately $0.16 million of additional salaries and share based compensation of predominately newly hired sales personnel as we expand our sales activities worldwide. This increase was partially offset by a decrease of approximately $0.1 million in advertising, travel and other related expenses. Selling and marketing expense as a percentage of revenue decreased from 22.8% in 2010 to 15.2% in 2011.

General and Administrative Expense. For the three months ended September 30, 2011, general and administrative expense increased 175.0% to approximately $2.5 million from $0.9 million during the same period in 2010. The increase in cost resulted primarily from an increase in share based compensation of $1.3 million, which predominately pertains to directors' compensation, approximately $0.2 million in legal fees related primarily to compliance with Securities and Exchange Commission standards, an increase in investor related activities of approximately $0.1 million due to us having been public during the three months ended September 30, 2011, but not during the same period in 2010, and an increase of $0.1 million in miscellaneous expenses. This increase was partially offset by a decrease of approximately $0.1 in audit and related expenses. General and administrative expense as a percentage of revenue increased to 125.2% in 2011 from 73.9% in 2010.

Financial Expenses. Financial expense remained relatively flat at $108,000 for the three months ended September 30, 2011, as compared to $121,000 during the same period in 2010. Our financial expenses reflect primarily changes in exchange rates, as well as interest related expenses. Financial expense as a percentage of revenue decreased to 5.4% in 2011, from 9.9% in 2010.

Tax Expenses. Tax expense remained relatively flat at $25,000 for the three months ended September 30, 2011, as compared to $9,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by approximately $1.5 million, or 169.5%, to $2.3 million for the three months ended September 30, 2011 from $0.8 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately $2.0 million (see above for explanations) and is partially offset by an increase of approximately $0.5 million in gross profit (see above for explanation).

Table of Contents

Nine months Ended September 30, 2011 Compared to Nine months Ended September 30, 2010

Revenues. For the nine months ended September 30, 2011, total revenue increased approximately $0.5 million, or 11.4%, to approximately $4.7 million from approximately $4.2 million during the same period in 2010. The $0.5 million increase was due to an increase in volume of approximately $0.6 million or approximately 14.2%, offset by an approximately $0.1 million decrease, or approximately 2.7%, due to price decreases. The following is an explanation of the approximately $0.5 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $2.0 million offset by a net decrease in deferred revenues of approximately $1.5 million.

For the nine months ended September 30, 2011, total gross revenue increased by approximately $2.0 million, or 85.3%, to approximately $4.4 million from approximately $2.4 million during the same period in 2010. This increase in total gross revenue is predominantly volume based, accounting for approximately $2.0 million or approximately 87.3%, with price decreases accounting for the remaining approximately $45,000, or approximately 2.0%. 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 MGuardTM. With respect to individual markets, this increase in gross revenue is mainly attributable to the first time shipment of approximately $1.2 million to our distributor in India during the first nine months of 2011, an increase of approximately $0.3 million of gross revenue from our distributor in Argentina, an increase of approximately $0.2 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 Israel, an increase of approximately $0.1 million of gross revenue from our new distributor in Russia, an increase of approximately $0.1 million of gross revenue from our new distributor in the Ukraine, an increase of approximately $0.1 million of gross revenue from our distributor in Mexico and approximately $0.1 million of gross revenue from our new distributor in the Netherlands. This increase was partially offset by a decrease of approximately $0.4 million in gross revenue from our distributor in Poland, a decrease of approximately $0.2 million in gross revenue from our distributor in Germany, a decrease of approximately $0.2 million from our distributor in Pakistan, and a decrease of approximately $0.1 million in gross revenue to our distributor in Kazakhstan. We also shipped and recognized gross revenue for approximately $0.4 million more from our remaining distributors during the nine months ended September 30, 2011, as compared to the same period in 2010.

For the nine months ended September 30, 2011, net deferred revenue recognized during the period decreased by approximately $1.5 million, or 81.0%, to approximately $0.4 million from approximately $1.9 million during the same period in 2010. The key driver of this decrease was volume based, accounting for approximately $1.4 million or approximately 77.4%, with the remaining approximately $0.1 million, or 3.6%, being driven by price decreases. 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 nine months ended September 30, 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, approximately $0.1 million to our distributor in Poland, and approximately $0.05 million to our distributor in Italy, 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 nine months period ended September 30, 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 nine months period ended September 30, 2011 accounted for purchases made in December 2010 that were not returned by the Brazilian distributor and were not yet recognized as revenues.

For the first nine months of 2010, net deferred revenue of approximately $1.9 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 $0.4 million, to our distributor in Sri Lanka of approximately $0.1 million and approximately $0.1 million to miscellaneous distributors. For the nine months ended September 30, 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 was only recognized during the first nine months of 2010 as revenues. As noted above, our distributor in Brazil has a contractual right to return all purchases for up to 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 $0.4 million recognized during the nine months period ended September 30, 2010 accounted for purchases made in December 2009 that were not returned and were not yet recognized as revenues.

Gross Profit. For the nine months ended September 30, 2011, gross profit (revenue less cost of revenues) increased 28.1%, or approximately $0.5 million, to approximately $2.4 million from approximately $1.9 million during the same period in 2010. Gross margin increased from 43.8% in the nine months ended September 30, 2010 to 50.3% in the nine months ended September 30, 2011. In addition to an increase in sales, we were able to improve our gross margin because of reduced production cost per stent driven by economies of scale. For the nine months ended September 30, 2011, our average selling price per stent recognized in revenue was $570, and we recognized the sale of 8,261 stents, compared to an average price of $643 per stent and 6,566 stents recognized in revenue for the same period in 2010. Our cost of goods sold per stent decreased from an average of $362 per stent recognized in revenue for the nine months ended September 30, 2010 to an average of $283 per stent for the same period in 2011. The higher price per stent for the nine months ended September 30, 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 nine months ended September 30, 2011, research and development expense increased 69.2% to approximately $1.6 million from approximately $1.0 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.8 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately $0.6 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately $0.2 million), offset by approximately $0.2 million reduction in miscellaneous expenses. Research and development expense as a percentage of revenue increased to 34.8% for the nine months ended September 30, 2011 from 22.9% in the same period of 2010.

Selling and Marketing Expense. For the nine months ended September 30, 2011, selling and marketing expense increased 47.1% to approximately $1.3 million, from approximately $0.9 million during the same period in 2010. The increase in selling and marketing expense resulted primarily from approximately $0.2 million of additional salaries and approximately $0.3 of share based compensation of predominately newly hired sales personnel as we expand 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, and a decrease of approximately $0.1 million in miscellaneous expenses. Selling and marketing expense as a percentage of revenue increased to 28.6% in 2011 from 21.7% in 2010.

General and Administrative Expense. For the nine months ended September 30, 2011, general and administrative expense increased 141.9% to approximately $4.9 million from $2.0 million during the same period in 2010. The increase in cost resulted primarily from an increase in share based compensation of $1.1 million which predominately

pertains to directors' compensation, an increase of approximately $0.4 million in salary expenses (due to an increase in employee infrastructure to accommodate and comply with Securities and Exchange Commission standards and reporting), an increase in investor related activities of approximately $0.4 million (due to us having been a publicly reporting company during the nine months ended September 30, 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 regarding a threatened lawsuit from a finder claiming a future success fee and commissions for assistance in finding our distributor in Brazil), and approximately $0.3 million in legal fees (also related primarily to compliance with Securities and Exchange Commission standards), and approximately $0.2 million increase in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 103.5% in 2011 from 47.7% in 2010.

Financial Expenses. For the nine months ended September 30, 2011, financial expense increased 496.7% to approximately $0.9 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 nine months ended September 30, 2010 that did not occur during the nine months ended September 30, 2011. This increase was partially offset by a decrease of approximately $0.1 million in miscellaneous expenses. Financial expense as a percentage of revenue increased from 3.5% in 2010, to 19.0% in 2011.

Tax Expenses. Tax expense remained relatively flat at $45,000 for the nine months ended September 30, 2011, as compared to $39,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by approximately $4.2 million, or 187.3%, to $6.4 million for the nine months ended September 30, 2011 from $2.2 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately $4.0 million (see above for explanations) and an increase of approximately $0.7 million in financial expenses (see above for explanation). This increase was partially offset by an increase in gross profit of approximately $0.5 million.

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Revenues. For the year ended December 31, 2010, total revenue increased 45.1% to $4.9 million from $3.4 million in 2009. The increase in revenue was primarily attributable to launching MGuard™ Coronary with bio-stable mesh in new markets around the world, particularly in Europe and Latin America.

Gross Margin. Our gross margin percentage for 2010 increased to 45.5% of revenues, compared to 32.8% during 2009. The increase in our gross margin resulted primarily from higher pricing, more efficient manufacturing and economies of scale due to the increase in sales volume.

Research and Development Expense. For the year ended December 31, 2010, research and development expense increased 0.6% to $1.338 million from $1.330 million 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 year ended December 31, 2010, selling and marketing expense increased 18.8% to $1.2 million from $1.0 million in 2009. The increase in cost resulted primarily from additional promotional activities worldwide. Selling and marketing expense as a percentage of revenue decreased to 25.0% in 2010 from 30.5% in 2009.

Table of Contents

General and Administrative Expense. For the year ended December 31, 2010, general and administrative expense increased 97.5% to approximately $2.9 million from $1.5 million in 2009. The increase in cost resulted primarily from a large increase in the amount of our share options being issued and the corresponding accounting charges and overall accounting and legal expenses. 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 year ended December 31, 2010, financial expense increased to approximately $0.2 million from income of $0.04 million 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 in 2010 and 2009. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased 25.6% to $3.4 million in 2010 from $2.7 million in 2009.

Backlog. Our order backlog at December 31, 2010 was approximately $1.5 million, up 165% compared to approximately $0.6 million at December 31, 2009.

Liquidity and Capital Resources

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

General. At September 30, 2011, we had cash and cash equivalents of approximately $7.5 million, as compared to $0.6 million at December 31, 2010. The increase is attributable primarily 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. 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 $3.9 million for the nine months ended September 30, 2011, and approximately $2.2 million for the same period in 2010. The principal reasons for the usage of cash in our operating activities for the nine months ended September 30, 2011 include a net loss of approximately $6.4 million, and a decrease in working capital of approximately $1.2 million, offset by approximately $2.8 million in non-cash share based compensation, and approximately $0.9 million in non-cash financial expenses related to the revaluation of a convertible loan.

Cash flow generated from investing activities was approximately $0.1 million during the nine months ended September 30, 2011, compared to approximately $0.1 million of cash used by investing activities during the same period in 2010. The principal reason for the increase in cash flow from investing activities was a decrease in restricted cash of approximately $0.2 million.

Cash flow generated from financing activities was approximately $10.8 million for the nine months ended September 30, 2011, and $2.7 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 the non-converted portion 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 $0.3 million.

As of September 30, 2011, our current assets exceeded current liabilities by a multiple of 3.2. Current assets increased approximately $7.6 million during 2011, mainly due to cash raised from the private placements in 2011, while current liabilities decreased approximately $0.3 million during the same period. As a result, our working capital surplus increased by approximately $8.0 million to approximately $7.9 million during the nine months ended September 30, 2011.

Credit Facilities. As of September 30, 2011, we had a long term loan in the amount of approximately $0.2 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years that began in April 2010 and ends in January 2012. According to the loan agreement, in case of an “exit transaction,” we will be required to pay to the bank an additional $0.25 million if the sum received in a “liquidity event” or the value of the company in an “IPO” is higher than $100 million.

Convertible Loans. Prior to September 30, 2011, we had a convertible loan with an aggregate principal amount outstanding of approximately $1.58 million that bore 8% interest. Following the share exchange transactions on March 31, 2011, $580,000 plus accrued interest converted into shares of our common stock. The remaining principle in the amount of $1.0 million was repaid on May 15, 2011.

Sales of Stock. For the nine months ended September 30, 2011, we issued an aggregate of 9,415,145 shares of common stock and warrants to purchase 6,709,073 shares of common stock for gross proceeds of approximately $12.0 million.

Table of Contents

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

General. At December 31, 2010, we had cash and cash equivalents of approximately $636,000, as compared to $376,000 in 2009. 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 overall working capital.

Cash used in our operating activities was approximately $2.7 million in 2010, and $1.5 million in 2009. The principal reasons for the decrease in cash flow from operations in 2010 included a $3.4 million net loss, a decrease of $1.6 million in deferred revenues offset by $1.6 million of non cash share based compensation expense and a $0.4 million increase in other working capital.

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

Cash flow generated from financing activities was approximately $3.0 million in 2010, and $0.7 million 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 a convertible loan of approximately $1.5 million, offset by the repayment of a long term loan in the amount of $0.3 million.

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

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and require companies to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, the amendments eliminate the residual method for allocating arrangement considerations. We do not expect the standard to have material effect on its consolidated financial statements.

Table of Contents

In January 2010, the Financial Accounting Standards Board updated the "Fair Value Measurements Disclosures". More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This update clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value, and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. This update will become effective as of the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. The adoption of the new guidance did not have a material impact on our consolidated financial statements.

In May 2011, the Financial Accounting Standards Board issued amended guidance and disclosure requirements for fair value measurements. These changes will be effective January 1, 2012 on a prospective basis. Early application is not permitted. These amendments are not expected to have a material impact to the consolidated financial results.

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.

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. 50,666,663 shares of 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.

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 7,500,000 shares 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.

27

Table of Contents

Overview

We are an innovative 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 (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 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, seamless and complete solution for these patients.

MGuardTM Sleeve – Microscopic View

We intend to use our MGuard™ technology in a broad range of coronary related situations in which complex lesions are required and make it an industry standard for treatment of acute coronary syndromes. We believe that patients will benefit from a cost-effective alternative with a greater 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 Canada, Southeast Asia, India and Latin America.

Our initial MGuard™ products incorporated a stainless steel stent. We replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as MGuard Prime™. We believe the new platform will be superior because cobalt-chromium stents are generally known in the industry to provide better outcomes and possibly even a reduction in major adverse cardiac events. We believe we can use and leverage the MGuard™ clinical trial results to market MGuard Prime™. MGuard Prime™ received CE Mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. MGuard™ refers to both our initial products and MGuard Prime™, as applicable.

Table of Contents

Our Industry

According to Fact Sheet No. 310/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 January 3, 2011 2011 MEDTECH OUTLOOK produced 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%, the revenues from global coronary stents 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 January 3, 2011 2011 MEDTECH OUTLOOK produced by the BMO (Bank of Montreal) Investment Banking Group, 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 MGuardTM 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.

MGuardTM 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;
- it 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
- it maintains the standards of a conventional stent and therefore should require little to no additional training by physicians.

29

Table of Contents

MGuardTM – Coronary Applications

Our MGuardTM Coronary with a bio-stable mesh and our MGuardTM Coronary with a drug-eluting mesh are aimed at the treatment of coronary arterial disease.

MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh. Our first MGuardTM product, the MGuardTM Coronary with a bio-stable mesh, is comprised of our mesh sleeve wrapped around a bare-metal stent. It received CE Mark approval in October 2007 and, in January 2008, we started shipping this product to customers and distributors in Europe. MGuard Prime™ with a bio-stable mesh is comprised of our mesh sleeve wrapped around a cobalt-chromium stent. In comparison to a conventional bare-metal stent, we believe the MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh provide protection from embolic showers. Results of clinical trials on the MGuardTM Coronary stent, including the MAGICAL, PISCIONE and MGuard international registry (iMOS) clinical trials described below (see "Business – Product Development and Critical Milestones - 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, as explained below (see "Business – Product Development and Critical Milestones - Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population" below). The results of these clinical trials for the MGuardTM Coronary stent suggest higher levels of myocardial blush grade 3 (occurrence in 73% of patients in the MAGICAL study and 90% of patients in the PISCIONE study, for the MGuardTM Coronary stent) and lower rates of 30 day and 1 year major adverse cardiac event rates, (2.4% and 5.9%, respectively, for the MGuardTM Coronary stent), as compared to the levels and rates of other bare-metal and drug-eluting stents, as reported by Svilaas, et. al. ("Thrombus Aspiration during Primary Percutaneous Coronary Intervention," New England Journal of Medicine, Volume 358, 2008). As reported in the study by Svilaas, et. al., myocardial blush grade 3 occurred in 32.2% of patients with a bare-metal stent and 45.7% 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 10.9% for patients with drug eluting stents. Myocardial blush grade refers to a 0-3 grade scale given to the adequacy of perfusion and blood flow through an area served by a coronary artery; the longer the blush persists, the poorer the blood flow and the lower the myocardial blush grade. Ndrepepa, et. al. ("5-Year Prognostic Value of No-Reflow Phenomenon After Percutaneous Coronary Intervention in Patients With Acute Myocardial Infarction," Journal of the American College of Cardiology, Volume 55, Issue 21, 2010) reported that high myocardial blush grades correlate with higher survival rates among affected patients. Sustained performance by the MGuardTM Coronary stent with respect to contributing to higher levels of myocardial blush grade 3 and lower rates of 30 day and 1 year major adverse cardiac event rates would differentiate the MGuardTM Coronary stent from other bare-metal and drug-eluting stents that do not offer such benefits.

MGuardTM Coronary with a drug eluting bio-absorbable mesh. Based upon the clinical profile of MGuardTM Coronary, we anticipate that the MGuardTM 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 MGuardTM 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. The bio-absorbability of MGuardTM 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 for the protective sleeve on the MGuardTM Coronary with a drug-eluting bio-absorbable mesh to 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. MGuardTM 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.

MGuardTM – 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. We believe that our MGuardTM 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 MGuardTM 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. 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.

Table of Contents

MGuardTM – 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. 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.

The Peripheral Artery Disease market consists of three segments: Aortic Aneurysm, Renal, Iliac and Bilary and Femoral-Popliteal procedures. Aortic Aneurysm is a condition in which the aorta, the artery that leads away from the heart, develops a bulge and is likely to burst. This condition often occurs below the kidneys, in the abdomen. Renal, Iliac and Bilary procedures refer to stenting in the kidney, iliac arteries (which supply blood to the legs) and liver, respectively. Femoral-Popliteal procedures involve stenting in vessels in the legs.

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 MGuardTM 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, “Q” stands for our fiscal quarter. 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 a timetable to seek U.S. Food and Drug Administration approval for our MGuardTM Coronary plus with bio-stable mesh product in our current business plan. We anticipate that our MGuardTM Coronary plus with bio-stable mesh product will be classified as a Class III medical device by the U.S. Food and Drug Administration. The use of the term “to be determined” in the table below with regard to certain U.S. Food and Drug Administration trial 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	Q1-2008	Q4-2014	Q4-2014
MGuard™ Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	Q1-2011	Q1-2012	Q2-2012	To be determined	To be determined
MGuard™ Carotid Plus Bio-Stable Mesh	Carotid Arteries	Q1-2011	Q1-2012	Q2-2012	To be determined	To be determined
MGuard™ Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	Q1-2013	Q3-2016	Q4-2016	To be determined	To be determined

We anticipate that our MGuardTM Coronary plus with bio-stable mesh product 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 MGuardTM Coronary with bio-stable mesh. We also performed all CE Mark required mechanical testing of the stent. We conducted pre-clinical animal trials at Harvard and MIT Biomedical Engineering Center BSET lab in July 2006 and August 2007. In these animal trials, on average, the performance of the MGuardTM 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
MGuardTM Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	CE Mark (European Union + Rest of World)	Q4-2006	Q3-2007
	Drug-Eluting Mesh (Bare-Metal Stent Plus Drug-Eluting Mesh)	CE Mark (European Union + Rest of World)	Q3-2013	Q4-2014
		FDA (U.S.)	To be determined	To be determined
	Cobalt-Chromium Stent Plus Bio-Stable Mesh	FDA	Q2-2011	Q4-2011
MGuardTM Peripheral/Carotid	Self Expending System Plus Mesh	CE Mark (European Union + Rest of World)	Q4-2011	Q1-2012
MGuardTM Carotid	Self Expending System Plus Mesh	FDA (U.S.)	Peripheral information on animals can be used	

With respect to the preclinical studies for MGuardTM Coronary, the drug-eluting mesh trials have been either delayed or indefinitely suspended and the start of the cobalt-chromium stent plus bio-stable mesh trial was delayed from our previously announced target by one fiscal quarter due to a delay in our receipt of anticipated funding.

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.

						Study Status		
Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Start	End Enrollment	End of Study
MGuardTM Coronary	Bare-Metal Stent Plus Bio-Stable	Germany – two sites	12 months	Study to evaluate safety and	41	Q4-2006	Q4- 2007	Q2-2008
			12 months		30	Q4-2007	Q1-2008	Q2-2009

Mesh	Brazil – one site Poland – four sites	6 months	performance of MGuardTM system	60	Q2-2008	Q3-2008	Q2-2009
	International MGuardTM Observational Study - worldwide - 50 sites	12 months		1,000	Q1-2008	Q4-2013	Q4-2013
	Israeli MGuardTM Observational Study - Israel - 8 sites	6 months		100	Q2-2008	Q3-2011	Q3-2012
	Master randomized control trial - 7 countries, 50 centers in South America, Europe and Israel	12 months		430	Q2-2011	Q1-2012	Q2-2013
	Brazil – 25 sites	12 months		500	Q3-2010	To be determined	To be determined
	FDA Study - 40 sites, U.S. and out of U.S.	12 months	Pilot study to evaluate safety and performance of MGuardTM system for FDA approval	800	Q1-2012 - Q2-2012	Q3-2013 - Q1-2014	Q4-2014 - Q2-2015
Drug-Eluting Stent (Bare-Metal Stent + Drug Eluting Mesh)	South America and Europe – 10 sites	8-12 months 12 months	Pilot study to evaluate safety and performance of MGuardTM system for FDA and CE Mark approval	500	To be determined	To be determined	To be determined
	U.S. – 50 sites			2,000	To be determined	To be determined	To be determined
	Rest of World as a registry study	8-12 months	Evaluation of safety and efficacy for	400	To be determined	To be determined	To be determined

specific
indications

Table of Contents

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Study Status Start	Study Status End Enrollment	Study Status End of Study
MGuardTM Peripheral	Self Expanding System + Mesh	South America and Europe – four sites	12 months	Pilot study to evaluate safety and performance of MGuardTM system for CE Mark approval	50	Q1-2012	Q3-2012	Q4-2014
		South America and Europe – six sites	6 months		150	Q2-2010	Q4-2010	Q2-2011
MGuardTM Carotid	Self Expanding System + Mesh	Rest of World as a registry study	6 months	Evaluation of safety and efficacy for specific indications post-marketing	200	Q2-2012	Q3-2013	Q3-2014

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.

With respect to the MGuardTM Coronary clinical trial for the Master randomized control trial, the start and end enrollment dates have been delayed from our previously announced target by a fiscal quarter and the end of study date has been delayed from our previously announced target by two fiscal quarters due to delays in the necessary approvals of the trial by local ethical committees in certain of the participant countries.
The MGuardTM 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 MGuardTM Peripheral clinical trial for the self expanding system + mesh, the start date has been delayed from our previously announced start date due to a delay in our receipt of anticipated funding.

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

As shown in the table above, we have completed five clinical trials with respect to our MGuardTM Coronary with bio-stable mesh. Our first study, conducted at two centers in Germany, included 41 patients with either saphenous vein graft coronary interventions or native coronary lesions treatable by a stenting procedure (blockages where no bypass procedure was performed). The MGuardTM 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 (2.5% of participants) had major 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 MGuardTM's safety in the treatment of vein grafts and native coronary legions.

Table of Contents

Our 2007 study in Brazil included 30 patients who were candidates for a percutaneous coronary intervention (angioplasty) due to 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). There were no major cardiac events at the time of the follow-up 30 days after the deployment of the stents.

The study 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 confirm the clinical performance of MGuardTM 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 restoration of electrocardiogram normality was achieved in 61% of patients. The total major adverse cardiac events rate during the six-month period following the deployment of the stents was 0%.

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

Our ongoing observation study in Europe is an open registry launched in the first fiscal quarter of 2009. This registry is expected to enroll up to 1,000 patients and is aimed at establishing the performance of MGuardTM 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 December 20, 2011, 501 patients of the prospective 1,000 have been enrolled in 28 sites.

Our ongoing observational study in Israel is an open registry launched in the fourth fiscal 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 December 20, 2011, 77 patients of the prospective 100 have been enrolled.

In the third fiscal 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 December 20, 2011, 17 patients of the prospective 500 have been enrolled.

Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population

We conducted a meta-analysis of data from four clinical trials in which MGuardTM 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;

- 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;

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the iMOS study, a Registry on MGuard 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.

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;

· 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; and

· 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.

Table of Contents

The meta analysis of MGuardTM 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 MGuardTM (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 MGuardTM) and ST segment resolution>70% (53.6% for the historical control and 79.1% for MGuardTM) are statistically significantly better with the MGuardTM. MGuardTM also appears consistently superior at the 30 days major adverse cardiac event (8.4% for the historical control and 2.4% for MGuardTM) and 1 year major adverse cardiac event (13.3% for the historical control and 5.9% for MGuardTM) 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

Trial	CADILLAC	Horizons-AMI	Horizons-AMI	TAPAS	TAPAS	EXPORT	EXPORT	EXPIRA	EXPIRA	REMEDIA	REM
Group	Stent + Abciximab	BMS	DES	Thrombus aspiration	control	control	TA	control	Thrombus aspiration	Thrombus aspiration	co
Number of Patients	524	749	2257	535	536	129	120	87	88	50	4